

# Exhibit 1

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Expert Report of Robin Cantor, Ph.D.**

**May 10, 2019**

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Table of Contents**

**I. Introduction ..... 1**

**A. Qualifications ..... 1**

**B. Assignment ..... 3**

**C. Summary of Opinions..... 5**

**D. Overview of Report ..... 13**

**II. Background ..... 13**

**A. U.S. Opioid History ..... 13**

**B. Pharmaceutical Markets, Pricing, and Volume ..... 15**

**III. Summary of Plaintiffs’ Experts’ Opinions ..... 17**

**A. Professor Meredith Rosenthal ..... 17**

**B. Professor David Cutler ..... 19**

**C. Professor Thomas McGuire..... 21**

**IV. Expert Report of Professor Rosenthal ..... 23**

**A. Professor Rosenthal’s analysis fails to capture certain important drivers of physician prescribing behavior and assumes Defendant manufacturer detailing is unlawful without analyzing the messaging content ..... 24**

**B. Professor Rosenthal’s direct model suffers from a number of problems related to her model specification and estimation ..... 35**

**C. Professor Rosenthal inadequately controls for increases in quantity demanded that can be explained by decreases in price ..... 49**

**D. Professor Rosenthal inadequately controls for factors in the but-for world that would shift (or mitigate shifts) in quantity demanded and supplied ..... 55**

**E. Professor Rosenthal does not provide an analysis of the relationship between alleged diversion and increased opioid volume ..... 62**

**F. Professor Rosenthal does not adequately consider uncertainty in her indirect approach ..... 63**

**V. Expert Report of Professor Cutler ..... 72**

**A. Professor Cutler’s analysis of harms suffers from inappropriate generalities based on mortality data and inconsistencies with Plaintiffs’ theory ..... 73**

**B. Professor Cutler’s direct model examines only the change between two periods of time, excluding effects that occur in the period in between ..... 83**

**C. Professor Cutler’s modeling of harms ignores benefits from reducing pain ..... 86**

**D. Professor Cutler creates variables to address missing data without sufficient evidence ..... 87**

**E. Professor Cutler does not adequately consider the role of the public sector in the measurement and cause of harms and related expenditures ..... 94**

**F. Professor Cutler does not appropriately examine the causality of diversion misconduct ..... 100**

**G. Professor Cutler’s inadequate consideration of uncertainty in his indirect approach undermines his opinions on but-for harms ..... 101**

**VI. Expert Report of Professor McGuire..... 106**

**A. Professor McGuire’s damages analysis relies on the reports of Professors Rosenthal and Cutler without validation..... 106**

**B. Professor McGuire’s damages methodology is based on the existence of unproven opportunity costs ..... 109**

**C. Professor McGuire’s data collection and treatments are not reproducible ..... 116**

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

D. Professor McGuire does not consider Plaintiffs’ duty to mitigate damages..... 119

E. Professor McGuire does not adequately consider the role of the public sector in Professor Cutler’s measurement of harms ..... 123

F. Professor McGuire’s methodology cannot disaggregate damages between marketing and diversion allegations or apportion damages among Defendants ..... 124

VII. Conclusions ..... 126

A. The Economic Framework uses associations to make inferences and estimate damages without proving causality ..... 127

B. The Economic Framework suffers from data and knowledge gaps that are being addressed through disregard, speculation, and anecdotal information as well as inconsistencies across baselines and estimation periods ..... 127

C. Plaintiffs’ Economics Experts have imposed certain artificial assumptions to simplify the characterization of the but-for world undermining the reliability of their results ..... 127

D. The uncertainties within Plaintiff Economics Experts’ analyses is compounded and expanded through the stages of the Economic Framework ..... 127

**Attachments**

- Attachment 1** – Curriculum vitae of Robin Cantor, Ph.D.
- Attachment 2** – Testimony Experience of Robin Cantor, Ph.D.
- Attachment 3** – Materials Considered



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**I. Introduction**

**A. Qualifications**

1. My name is Robin Cantor. I am a Managing Director in the Washington DC office of the Berkeley Research Group (“BRG”). I specialize in applied economics; health, environmental and energy economics; statistics; and risk management. I have a B.S. in mathematics from Indiana University of Pennsylvania with a specialization in statistics and a Ph.D. in economics from Duke University with a specialization in econometrics.
2. My responsibilities include conducting complex economic, statistical, and risk analyses for consulting, litigation support, and expert testimony, as well as managing a staff of internal and external professionals.
3. Prior to joining BRG, I held managerial and leadership positions at numerous companies and organizations:
  - a. I was a Principal Scientist at Exponent, Inc., where I led a group in the Health Sciences practice specializing in economics at the interface of science and technology.
  - b. I was a Managing Director in the Insurance and Claims Services practice of Navigant Consulting, Inc. I led the Liability Estimation and Insurance Coverage practice.
  - c. I was a Principal and Managing Director of the Environmental and Insurance Claims Practice of LECG, LLC.
  - d. I was the Program Director for Decision, Risk, and Management Sciences, a research program of the National Science Foundation (“NSF”), and a senior researcher at Oak Ridge National Laboratory. I am a past Coordinator and grants manager for the NSF Human Dimensions of Global Change, the NSF Methods and Models for Integrated Assessment, and the NSF/EPA Decision Making and Valuation for Environmental Policy.
  - e. I held faculty and advisory appointments in the Graduate Part-Time Program in Environmental Engineering, Science, and Management at the Johns Hopkins University.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

4. I have more than 30 years of research, teaching, and consulting expertise. My testimonial experience includes analysis of economic damages in commercial litigation, economic analysis of class certification issues, reimbursement and pricing in healthcare services, product liability estimation in litigation, bankruptcy, and insurance disputes, statistical analysis of asbestos settlements, cost contribution allocation in environmental and Superfund disputes, and reliability of survey methodology, statistical models, and estimation methods.
5. I have been qualified in state and federal court as an expert on economic damages, economics (including microeconomics, econometrics, cost-benefit analysis, and cost-benefit methodologies), risk management, and claims analysis in healthcare and other insurance matters.
6. I have been engaged as an economics expert in a number of healthcare matters including *In re Aetna UCR Litigation* (US District Court, District of New Jersey); *Hooman M. Melamed, M.D.*, *Hooman M. Melamed, M.D., Inc.*, and *Navid Navizadeh, M.D. et al. v. Kaiser Foundation Health Plan, Inc., et al.* (Superior Court of the State of California, County of Los Angeles); *Aetna Health Inc. and Aetna Life Insurance Company v. Deepak Srinivasan, M.D., et al.* (Superior Court of New Jersey, Camden County); *Ameritox, Ltd. v. Millennium Laboratories, Inc.* (US District Court, Middle District of Florida); and *Protest of TriWest Healthcare Alliance Corporation* (US GAO).
7. I joined other prominent economists and social scientists in an amicus curiae brief submitted to the U.S. Supreme Court in *Tyson Foods, Inc. v. Bouaphakeo et al.* (No. 14-1146) regarding the reliability of “average” or statistical evidence in class actions.
8. I have published scholarly articles and presented research at professional conferences on numerous areas of economic analysis including but not limited to health economics. I have submitted analysis, testimony and affidavits in federal arbitration, regulatory and Congressional proceedings, and federal and state courts. My publications include refereed journal articles, book chapters, expert reports, reports for federal sponsors, a co-authored book on economic exchange under alternative institutional and resource conditions, and an edited book on product liability.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

9. I am a member of the Society for Risk Analysis, the American Economic Association, the American Bar Association, and the Women’s Council on Energy and the Environment. I serve or have served on science review and advisory panels for the National Academies of Science, the National Science Foundation, the Johns Hopkins University Graduate Part-Time Program in Environmental Engineering and Science, the National Center for Environmental Decision-making Research, the Carnegie Council on Ethics and International Affairs, the National Oceanic and Atmospheric Administration, the National Academy of Public Administration, the Consortium for International Earth Science Information Network, and the Center for Climate and Energy Decision Making at Carnegie Mellon University. I am a past President of the Women’s Council on Energy and the Environment and a Fellow of the Society for Risk Analysis. I was the 2002 President of the Society for Risk Analysis. In 2001, I was appointed as a member of the Research Strategies Advisory Committee of the U.S. Environmental Protection Agency’s Science Advisory Board. I am a past President of the Board of Directors for MATRIX, The Business Center for Women and Minorities. I have served on the editorial boards of the *Journal of Risk Analysis* and the *Journal of Risk Research*.
10. My curriculum vitae is attached as **Attachment 1** to this report. My testimonial experience in the last four years is attached as **Attachment 2**. My current billing rate for this engagement is \$700/hour for analysis and testimony. Other BRG staff members have also worked at my direction on this matter, and they have hourly rates ranging from \$150-\$675.

**B. Assignment**

11. I understand the County of Cuyahoga, Ohio and the County of Summit, Ohio (collectively, “Bellwethers”, “Plaintiffs”, or “Track 1 Jurisdictions”) have filed complaints against pharmaceutical manufacturers, distributors, and pharmacies (collectively “Defendants”) in the matter captioned *In re National Prescription Opiate Litigation*.<sup>1</sup> I have been engaged by Ropes & Gray LLP (“Counsel”) on behalf of Mallinckrodt LLC and SpecGx LLC, to provide

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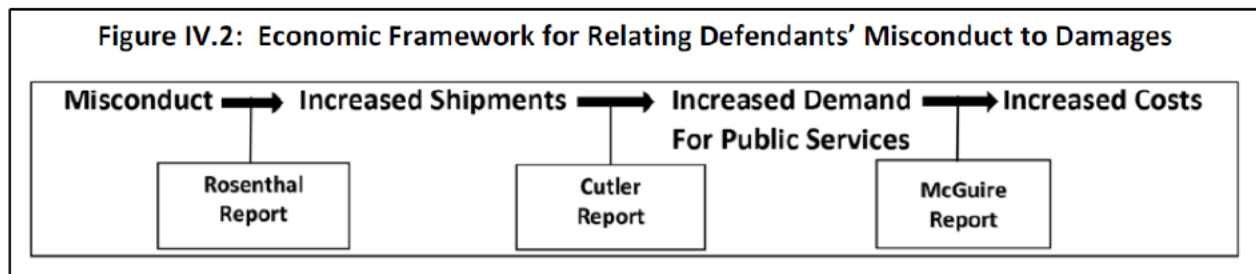
<sup>1</sup> County of Cuyahoga, OH’s Second Amended Corrected Complaint. ¶ 466, *In re National Prescription Opiate Litigation*, Case No. 1:17-MD-2804 (N.D. Ohio May 30, 2018); County of Summit, OH’s Corrected Second Amended Complaint. & Jury Demand, *In re National Prescription Opiate Litigation*, Case No. 1:17-MD-2804 (N.D. Ohio May 29, 2018).

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

an expert opinion with respect to the causation and damages methodology proffered by Plaintiffs in the matter.

12. Plaintiffs' economic framework for "relating defendants' misconduct to damages" ("Economic Framework") is presented through the expert reports of the following individuals: Professor Meredith Rosenthal,<sup>2</sup> Professor David Cutler,<sup>3</sup> and Professor Thomas McGuire<sup>4</sup> ("Plaintiffs' Economics Experts"). Exhibit 1 is a reproduction from Professor McGuire's expert report that indicates the relationship between the three expert reports in establishing Plaintiffs' Economic Framework. My assignment is to assess this framework and offer opinions regarding its economic foundations and reliability to establish causation and estimate damages, if any, due to Defendants' conduct as alleged by the Bellwether Plaintiffs ("Alleged Conduct").<sup>5</sup> Alleged Conduct includes Plaintiffs' allegations of marketing and diversion actions by Defendants related to at-issue opioid products during the relevant time period.<sup>6</sup>

**Exhibit 1: Plaintiffs Experts' Economic Framework<sup>7</sup>**



<sup>2</sup> See Expert Report of Professor Meredith Rosenthal, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019) ("Rosenthal Report").

<sup>3</sup> See Expert Report of Professor David Cutler, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019) ("Cutler Report").

<sup>4</sup> See Expert Report of Professor Thomas McGuire: Damages to Bellwethers, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019) ("McGuire Damages Report").

<sup>5</sup> I assess Professor McGuire's "Regarding Public Nuisance" report to the extent that it relies on any analysis, findings, and opinions found in the McGuire Bellwether Damages report. I reserve the right to evaluate Professor McGuire's specific public nuisance opinions related to past values of alleged externalities from opioid shipments, if any, to the extent Plaintiffs claim they represent damages or abatement costs, which they do not. See Expert Report of Professor Thomas McGuire: Regarding Public Nuisance, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019) ("McGuire Public Nuisance Report").

<sup>6</sup> None of the opinions of Plaintiffs' Economics Experts I have reviewed establish (or purport to establish) that any harm or damages were caused by manufacturers' conduct with respect to suspicious order monitoring or diversion. If Plaintiffs put forward a model purporting to establish such a causal link, I reserve the right to supplement my opinion.

<sup>7</sup> See McGuire Damages Report, at p. 10, Figure IV.2.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

13. In order to provide my expert opinion, I reviewed publicly available information, case pleadings, deposition testimony, and certain documents received from Counsel that were previously produced in this matter. **Attachment 3** and the footnotes of this report contain the information I considered to arrive at my opinions.
14. My findings and opinions are based on my understanding of the information available to me as of the date of this report and my experience and training as an economist. I understand that discovery is still ongoing and that additional materials may become available to me. I therefore expect that should additional relevant materials be made available to me after the submission date of this report, I will consider such information as necessary. I reserve the right to supplement this report based upon any additional work that I may conduct or supervise from my review of such materials.

**C. Summary of Opinions**

**1. Plaintiffs' Economic Framework**

15. The Economic Framework presented through the analyses and opinions of Professors Rosenthal, Cutler, and McGuire, individually and in combination, do not prove causality or provide reliable estimates of damage components or overall damage calculations, for the reasons that I explain below.
16. Plaintiffs' Economics Experts' opinions all suffer from the following reliability issues:
  - a. The Economic Framework uses associations to make inferences and estimate damages without proving causality, and by doing so, Plaintiffs' Economics Experts are avoiding a rigorous analysis of many obvious factors that would confound a causality opinion. Plaintiffs' Economic Experts ignore many influences that are not derived from the Alleged Conduct or which are complicated by the clear roles of non-Defendants. As a result, the Economic Framework treats diversion as a residual outcome when it is in fact a considerable factor in Plaintiffs' damage claim.
  - b. The Economic Framework used by Plaintiffs' Economics Experts suffers from data and knowledge gaps that are being addressed through disregard, speculation, and anecdotal information. Importantly, the Economic framework is missing information and factors in the real world that likely would increase predicted values

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

of but-for shipments and harms due to factors completely unrelated to Plaintiffs' allegations. As a result, Plaintiffs' Economics Experts' analyses fall far short of meeting any acceptable economic standards in attributing causality. Additionally, the Economic Framework used by Plaintiffs' Economics Experts suffers from critical inconsistencies. For example, there is no consistency in the selection of baseline conditions. Exhibit 2 summarizes these varying baselines (i.e. reference points for the models) and the subsequent estimates that are based on the relationship established in the baselines.

**Exhibit 2: Summary of Plaintiffs' Economics Experts' Inconsistent Baseline and Far Reaching Estimate Time Periods<sup>8</sup>**

Expert	Model	Baseline Period	Period of Estimated Results	# of Years Between Baseline and Latest Estimate
Professor Rosenthal	Indirect	1997	1995-2016	19
Professor Cutler	Indirect All Opioid	1993-1995	2011-2016	21
Professor Cutler	Indirect Illicit Opioid	2008-2010	2011-2016	6
Professor McGuire	Damages	Uses both Professor Rosenthal and Professor Cutler's estimates as inputs	2006-2018	N/A

- c. Plaintiffs' Economics Experts make artificial assumptions to simplify the crucial characterization of the but-for world that are necessary for their causation analysis and damages calculation. These assumptions fail to adequately account for the but-for marketing (type and amount), the supply of illicit opioids, the conduct of criminal actors (e.g., pill mills) of the at-issue opioids, and the consequent but-for harms, if any, from these factors. For example, Professor Rosenthal assumes, without adequate justification, that but-for detailing would match the magnitude and temporal pattern as observed for non-defendants. As another example, Professor Cutler apparently assumes that avoided harms due to pain treatment in the real world are zero—that is, that pain treatment does not reduce any harms. Consequently, none of the experts (including Professor McGuire) address the unobservable harms that may have occurred in the absence of opioid pain treatments. Professor Cutler also assumes that illicit opioid consumption is due to

<sup>8</sup> See Rosenthal Report, at ¶ 83 and Table 5; Cutler Report, at ¶ 97, Figure III.5, ¶ 98, and Figure III.6; McGuire Damages Report at ¶¶ 15-16 and 70-71.



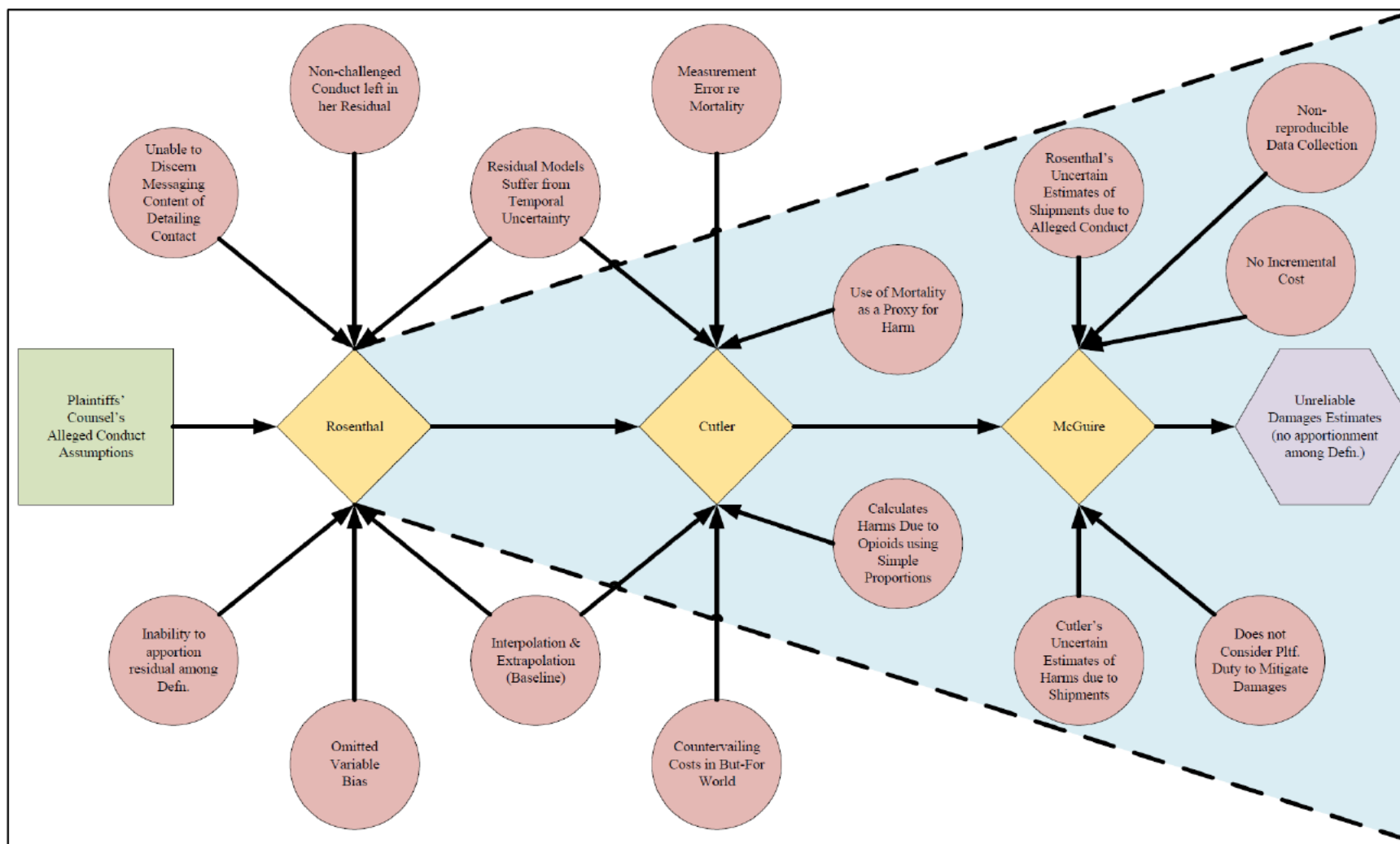
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the Defendants' Alleged Conduct and not related to public-sector drug enforcement failures to contain illegal drug activities. Such assumptions fail to acknowledge or explicitly model the role of key participants in the opioid crisis (e.g., FDA, DEA, federal health insurance regulations, criminal elements, actors in the illegal supply chain, etc.). Due to these oversimplified assumptions made by Professors Rosenthal and Cutler, Professor McGuire's final estimation of damages relies on inadequate support to prove Plaintiffs' allegations, nor does he provide an economically sound basis to attribute and apportion causality among Defendants, and in particular Mallinckrodt.

- d. As shown above in Exhibit 1, the analyses of Plaintiffs Economics Experts' are consecutively related. Importantly, substantial uncertainties are evident in each link of the structure (from Rosenthal to Cutler to McGuire) that makes up the Economic Framework. Moreover, my review indicates that these uncertainties are unlikely to be offsetting. As a result, the uncertainty of the final damages calculations that, by design in the Economic Framework, rely on numerous preceding framework components will be at least as great, and more likely, much greater than the uncertainty of any single preceding component. Plaintiffs Economics Experts neither have adequately addressed the compounding and expanding uncertainties in the design of the Economic Framework nor the implication of these uncertainties for the reliability of Professor McGuire's damage calculations. Exhibit 3 illustrates the many sources of uncertainty and how they cascade in the Economic Framework, and render it less certain at each consecutive step.
17. As a sequenced model, the Economic Framework propagates the uncertainty of each expert's analysis into the next stage of analysis. Exhibit 3 provides a summary of the knowledge gaps, questionable assumptions, and uncertainty issues that I address in greater detail for each of the components that I review in this report.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 3: Diagram of Expanding Error and Cascading Uncertainty**





## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 4: Summary of Cantor Opinions Related to each of Plaintiffs' Economics Experts**

<b><u>Rosenthal Report</u></b>	<b><u>Cutler Report</u></b>	<b><u>McGuire Report</u></b>
<ul style="list-style-type: none"> <li>• Prescriber detailing is assumed to be a measure of Alleged Conduct without any analysis of the detailing message content. Promotion is simply assumed to be unlawful.</li> <li>• Measures an artificial association between detailing and prescriptions by combining opioid molecules into one market</li> <li>• Estimated depreciation of detailing is a convenient device used to guarantee desired results and cannot be justified by the products' addictive properties</li> <li>• Inadequate control for shifts in supply that cause movements along the true demand curve (e.g., generic pricing)</li> <li>• Inadequate control for other factors in the but-for world that shifted the demand curve or mitigated shifts (e.g., regulation, insurance coverage, costs of alternative treatments, physicians' positions on pain, cultural despair)</li> <li>• No analysis of the relationship between alleged diversion and excess opioid volume</li> <li>• Inadequate consideration of uncertainty in the indirect approach (actuals are within the prediction intervals)</li> </ul>	<ul style="list-style-type: none"> <li>• Shipments-to-harms theory is inconsistent with the measured harms for Cuyahoga and Summit counties (e.g., Summit has more shipments but similar mortality and lower damages as compared to Cuyahoga)</li> <li>• Modeling of harms ignores benefits from reducing pain</li> <li>• Uses speculation and extrapolation to fill many data gaps</li> <li>• Inadequate consideration of the role of the public sector in measurement of harms (e.g., law enforcement's role in minimizing the supply of fentanyl and diversion control, use of naloxone for overdoses, and response to crime)</li> <li>• Does not properly examine the causality of diversion Alleged Conduct and simply acts as a calculator</li> <li>• Inadequate consideration of uncertainty in the indirect approach (actuals are within the prediction intervals)</li> </ul>	<ul style="list-style-type: none"> <li>• Relies on Rosenthal and Cutler without validation</li> <li>• Relies on a theory of unproven opportunity costs for damages</li> <li>• Data collection and treatments are not reproducible</li> <li>• No consideration of counties' duty to mitigate damages</li> <li>• Inadequate consideration of the role of the public sector in Professor Cutler's measurement of harms</li> <li>• No methodology to disaggregate damages between marketing and diversion allegations or apportion damages among defendants</li> </ul>

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

## **2. Professor Meredith Rosenthal**

18. Professor Rosenthal's analyses and opinions suffer from the following reliability issues:

- a. Professor Rosenthal does not rigorously analyze her detailing measure and she does not opine on the but-for level of detailing for the Defendant manufacturers.
- b. Professor Rosenthal's model fails to reflect the relationships within the market for each opioid molecule and measures an artificial association by combining opioid molecules (e.g., hydrocodone, oxycodone, etc.) into one market. Her estimated depreciation rate lacks an adequate economic foundation and is only a convenient device to guarantee her assumed causal relationship between marketing and prescribing, as shown through the inconsistencies when estimating for specific opioid molecules. Her preferred direct model will find a positive and significant relationship at least between any non-negative random variable and opioid volumes.
- c. Professor Rosenthal inadequately controls for shifts in supply that cause movement along the true demand curve (e.g., entry of generic products, which would reduce price and therefore increase quantity demanded) or factors in the but-for world that would have shifted or mitigated shifts in the demand curve (e.g., federal and state rules, incentives to increase patient satisfaction, insurance coverage and cost of alternative treatments, physicians' attitude towards pain treatment, and cultural despair).
- d. Despite her role as Plaintiffs' causation expert (and first "link" in the chain between her, Cutler, and McGuire), Professor Rosenthal makes no attempt to address what I understand to be Plaintiffs' diversion-based theories of liability against Mallinckrodt, or any Defendant, at all. Professor Rosenthal does not provide a direct analysis of the relationship between the diversion Alleged Conduct and excess opioid volume. Her report is limited to marketing Alleged Conduct. Her indirect analysis attempts to assess marketing Alleged Conduct not related to detailing. Her analysis does not rule out other causal factors unrelated to marketing Alleged Conduct. Therefore, Professor Rosenthal's analyses are inadequate to address marketing causality and she has no opinions related to diversion causality.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

- e. Professor Rosenthal does not adequately consider substantial uncertainty in her indirect model. When the prediction error over time is considered, I show that her indirect modeling results cannot rule out that actual shipment amounts are within the bounds of the prediction interval for shipments in the absence of the Alleged Conduct. Thus, the interval results that I consider for her model do not rule out that excess shipments are zero.

**3. Professor David Cutler**

19. Professor Cutler's analyses and opinions suffer from the following reliability issues:

- a. Professor Cutler's analysis fails to consider certain inconsistencies that suggest his theory is incomplete at best. For example, Professor Cutler does not consider demographic differences between patients who consume licit opioids and people who overdose on opioids (licit or illicit). In addition, the data for the Bellwethers indicate very different licit opioid shipments per capita, but the mortality rate impacts as measured by Professor Cutler are the same for Cuyahoga and Summit counties. Also missing from Professor Cutler's analysis is proof that shipments of licit product grew the demand for illicit product and the associated harms or consideration that some illicit drug use would have developed independently of licit use.
- b. There are likely unobservable benefits from opioids, including shipments that would increase the predicted but-for level of harm as measured by Professor Cutler. In his analysis, Professor Cutler has not demonstrated a net measure of harm, he has only demonstrated the association between the actual shipments and harm. Professor Cutler's association does not include harms avoided under actual pain treatment conditions through which some patients prolong their lives, are more productive, and act more responsibly to meet their family's needs. These harms are unobservable in the actual world, because they are avoided, but would manifest in the but-for world. Disregarding this countervailing benefit leads to an overestimate of the difference in harms in the actual and but-for worlds, or what Professor Cutler measures as excess harms.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

- c. At numerous points in his analysis, Professor Cutler interpolates and adjusts variables to address missing data problems with very little foundation or information. For at least two important calculations, Professor Cutler relies on one year's data value to infer values for approximately a dozen other years.
- d. Professor Cutler does not adequately consider the role of the public sector in measurement of harms and related expenditures. Importantly, he assumes that all of the substantial increase in heroin and fentanyl use is due to unmet demand for licit drugs. He fails to consider that DEA and other law enforcement played a role in the influx in supply of illicit opioids. Moreover, Professor Cutler does not consider the role of criminal organizations and illegal supply in driving illicit opioid volume.
- e. Professor Cutler does not appropriately examine the causality of diversion Alleged Conduct. He uses Professor Rosenthal's estimates of shipments due to marketing Alleged Conduct, which, as described above, do not address diversion causality, and he simply acts as a calculator using information on diversion activity without direct analysis. To the extent he specifically addresses diversion activity, it only pertains to distributor Alleged Conduct, not manufacturer Alleged Conduct or the conduct of pharmacies, physicians, or patients.
- f. Professor Cutler does not adequately consider the substantial uncertainty in his indirect model. When the prediction error over time is considered, I show that his indirect modeling results cannot rule out that actual harms are within the bounds of the prediction interval for harms in the absence of the Alleged Conduct. Thus, the interval results that I consider for his model do not rule out that excess harms are zero.

**4. Professor Thomas McGuire**

20. Professor McGuire's analyses and opinions suffer from the following reliability issues:

- a. Professor McGuire's damages estimates rely on Professor Rosenthal and Professor Cutler without validation to prove causality.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

- b. Professor McGuire’s methodology to collect expenditure data and treatments is ad hoc and not reproducible, and his damages estimates are speculative due to information gaps.
  - c. Professor McGuire’s damages methodology is based on the existence of unproven opportunity costs.
  - d. Professor McGuire does not consider the municipalities’ duty to mitigate damages.
  - e. Professor McGuire does not adequately consider the role of the public sector or patients in Professor Cutler’s measurement of harms and subsequent application of Professor Cutler’s measurement of harm to municipalities’ expenditures.
  - f. Professor McGuire’s methodology cannot disaggregate damages between marketing and diversion allegations or apportion damages among Defendants.
21. Because each component of the Economic Framework suffers from potential downward bias in the but-for predictions, the product of these components is also likely to be biased downward. As a result, Professor McGuire’s damages are overstated.

**D. Overview of Report**

22. Section II of this report provides a U.S. background of the history of opioids and the pharmaceutical supply chain. Section III summarizes the opinions of Plaintiffs’ Economics Experts. Sections IV, V, and VI present my opinions regarding the methodology and conclusions of each Plaintiffs’ Damages Expert, and Section VII contains my conclusions regarding Plaintiffs’ Economics Experts’ Economic Framework.

**II. Background**

**A. U.S. Opioid History**

23. I understand, based in part on Plaintiffs’ Experts’ reports, that prior to the current opioid epidemic (estimated to have begun in the 1990s), there were three opioid epidemics. The first involved opium and morphine around 1870 to the mid-1890s. The second (late 1940s

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

to early 1950s) and the third (late 1960s to early 1970s) involved heroin.<sup>9</sup> Morphine was used to treat pain during the 19th century, and heroin was initially introduced in the late 19<sup>th</sup> century as a “non-addictive alternative to morphine.”<sup>10</sup> Recognition of heroin’s addictive properties resulted in early 20<sup>th</sup>-century regulation that limited the use of morphine and heroin as pain treatments.<sup>11</sup> The surge of heroin abuse in the late 1960s and early 1970s was partly due to soldiers exposed to the drug during the Vietnam War. This epidemic contributed to a generation of long-term drug users that continued to survive with a semi-functional heroin addiction.<sup>12</sup>

24. The 1970s Controlled Substance Act (CSA) formalized a scheduling system, which “allowed the FDA in consultation with BNDD (later DEA) to sort drugs into five categories according to their therapeutic value and abuse potential.”<sup>13</sup> Heroin was included with other outlawed drugs under Schedule I.<sup>14</sup> Most prescription opioids were classified as Schedule II drugs, but hydrocodone combination products were listed as Schedule III until it was rescheduled to Schedule II in October 2014.<sup>15</sup> The CSA strengthened the closed system of distribution for opioid products: “transactions could lawfully occur only among authorized registrants...Scheduled drugs were to remain under the control of registrants, and only registrants, until such time as they reached their intended medical users.”<sup>16</sup>

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<sup>9</sup> See, e.g., Expert Report of Professor David Courtwright, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019) (“Courtwright Report”), at p. 8; Expert Report of Professor Jonathan Gruber, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019) and supporting materials (“Gruber Report”), at ¶ 21.

<sup>10</sup> See Gruber Report, at ¶ 20.

<sup>11</sup> See Gruber Report, at ¶ 20.

<sup>12</sup> See, e.g., Stobbe, Mike. “Today’s Opioid Crisis Shares Chilling Similarities with Past Drug Epidemics.” *Chicago Tribune*, Chicago Tribune, 28 Oct. 2017, [www.chicagotribune.com/news/nationworld/ct-drug-epidemics-history-20171028-story.html](http://www.chicagotribune.com/news/nationworld/ct-drug-epidemics-history-20171028-story.html); Jamison, Peter. “Falling Out: A generation of African American heroin users is dying in the opioid epidemic nobody talks about. The nation’s capital is ground zero.” *The Washington Post*, 18 Dec. 2018, [https://www.washingtonpost.com/graphics/2018/local/opioid-epidemic-and-its-effect-on-african-americans/?utm\\_term=.7cce3d9b4026](https://www.washingtonpost.com/graphics/2018/local/opioid-epidemic-and-its-effect-on-african-americans/?utm_term=.7cce3d9b4026).

<sup>13</sup> See Courtwright Report, at p. 38.

<sup>14</sup> See Courtwright Report, at p. 8.

<sup>15</sup> See Courtwright Report, at pp. 37-38; 21 CFR Part 1308, Drug Enforcement Administration, “Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II,” (Aug. 22, 2014), available at [https://www.deadiversion.usdoj.gov/fed\\_regs/rules/2014/fr0822.htm](https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm).

<sup>16</sup> See Courtwright Report, at pp. 38-39.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

25. In the late 1980s and early 1990s, medical and healthcare professionals began calling for change surrounding the treatment of pain.<sup>17</sup> By the mid-1990s, provider practices related to prescription opioids began to change, and the volume of these products in the market continued to grow through late 2011.<sup>18</sup> Prescription opioids are legal products that can be prescribed by physicians to treat pain. There are several opioid molecules that are currently sold as prescription opioids, but some of the most common molecules are oxycodone, hydrocodone, fentanyl, and morphine.<sup>19</sup> From the mid-2000s forward, the United States experienced increasing overdose deaths related to opioids.<sup>20</sup>

**B. Pharmaceutical Markets, Pricing, and Volume**

26. In order to discuss allegations in this matter, it is important to understand how prescription drugs are distributed and paid for in the U.S. Exhibit 5 illustrates the pharmaceutical market and payment process in the U.S.
27. Pharmaceutical manufacturers produce prescription drugs and sell the product to wholesalers (also known as a distributors). Then, wholesalers distribute and sell the product downstream to pharmacies.<sup>21</sup> The pharmacies dispense the product to patients, who receive prescriptions from physicians, and collect the applicable copayment or coinsurance determined by the patients' health insurance coverage. The pharmacies bill the pharmacy benefit managers (PBM) of patients' plan sponsors for the balance not covered by the patients' payments, based on the rate established by contracts between the pharmacies and PBMs. PBMs, in

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<sup>17</sup> See, e.g., Dayer, L., Jacob T. Painter, Kelsey McCain, Jarrod King, Julia Cullen & Howell R. Foster, "A recent history of opioid use in the US: Three decades of change," *Substance Use & Misuse*, 54:2, 331-339 (2019), at pp. 332-333.

<sup>18</sup> See, e.g., Dayer, L., Jacob T. Painter, Kelsey McCain, Jarrod King, Julia Cullen & Howell R. Foster, "A recent history of opioid use in the US: Three decades of change," *Substance Use & Misuse* 54:2, 331-339 (2019), at pp. 333-334. See also, Rosenthal Report, at p. 41, Figure 5.

<sup>19</sup> See, e.g., Center for Disease Control and Prevention, "Opioid Basics," available at <https://www.cdc.gov/drugoverdose/opioids/index.html>.

<sup>20</sup> See, e.g., Jalal, H. et al., "Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016," *Science* 361, 1218 (Jan. 17, 2019), at p. 1.

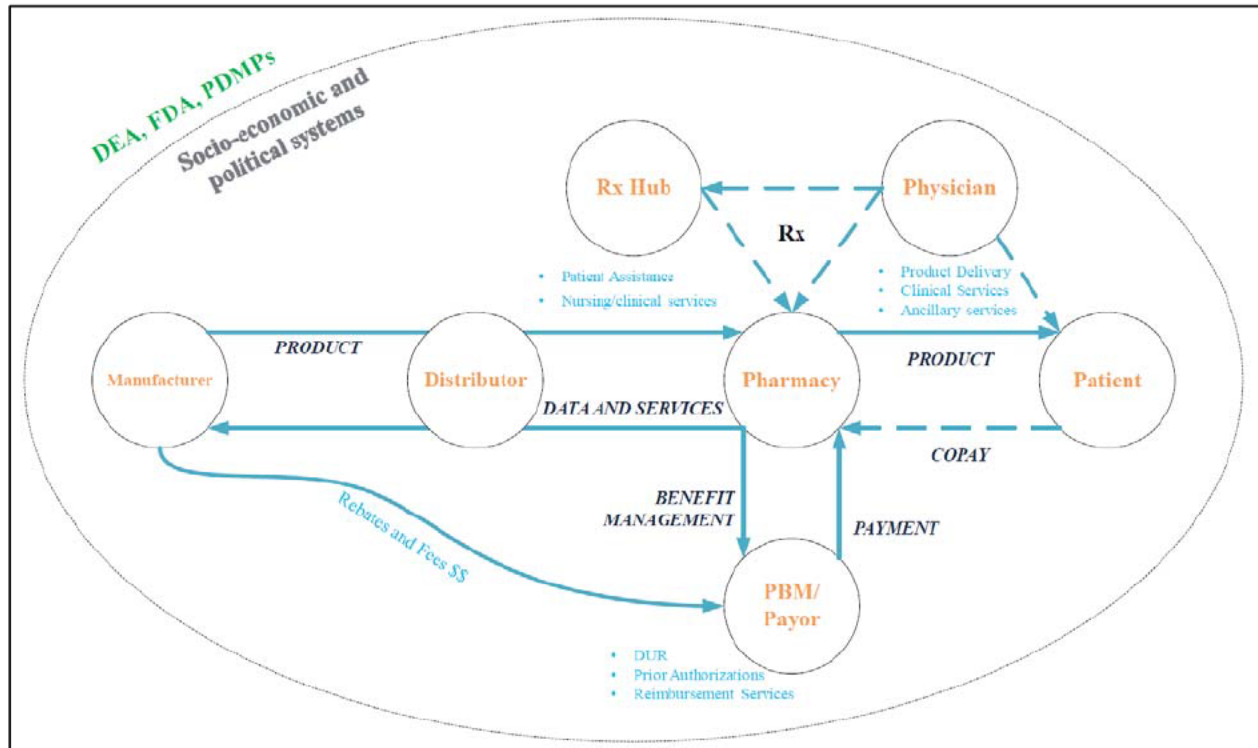
<sup>21</sup> In some instances, manufacturers sell directly to pharmacies. Whether buying through a wholesaler or directly from a manufacturer, pharmacies often negotiate discounts on drug purchases.



## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

turn, pay pharmacies and bill their clients (i.e. the plan sponsors), according to contracts with each plan sponsor.<sup>22</sup>

**Exhibit 5: Pharmaceutical Markets**



28. The price of the opioid product varies at multiple stages of the pharmaceutical market. For example, the price to the patient is determined based on the patient's health insurance coverage, whereas the price to the plan sponsor is determined based on the PBM's contracts with the plan sponsor and pharmacies as well as any manufacturer rebates shared by the PBM and plan sponsor.<sup>23</sup>

<sup>22</sup> See, e.g., MedPac, "Overview: The drug development and supply chain," (Jun. 16, 2016) available at <http://www.medpac.gov/docs/default-source/fact-sheets/overview-of-the-drug-development-and-supply-chain.pdf?sfvrsn=0>, at slides 12-16; Sood N., et al. "The Flow of Money Through the Pharmaceutical Distribution System," Schaeffer Center for Health Policy & Economics, University of Southern California (Jun. 2017), available at [https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC\\_Flow-of-MoneyWhitePaper\\_Final\\_Spreads.pdf](https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC_Flow-of-MoneyWhitePaper_Final_Spreads.pdf), at p. 2; Academy of Managed Care Pharmacy, "AMCP Guide to Pharmaceutical Payment Methods," available at [http://www.amcp.org/data/jmcp/JMCPSUPPC\\_OCT07.pdf](http://www.amcp.org/data/jmcp/JMCPSUPPC_OCT07.pdf), at pp. S4-S5.

<sup>23</sup> See, e.g., Academy of Managed Care Pharmacy, "AMCP Guide to Pharmaceutical Payment Methods," available at [http://www.amcp.org/data/jmcp/JMCPSUPPC\\_OCT07.pdf](http://www.amcp.org/data/jmcp/JMCPSUPPC_OCT07.pdf), at p. S3; Sood N., et al. "The Flow of Money Through the Pharmaceutical Distribution System," Schaeffer Center for Health Policy & Economics, University of Southern California (Jun. 2017), available at [https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC\\_Flow-of-MoneyWhitePaper\\_Final\\_Spreads.pdf](https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC_Flow-of-MoneyWhitePaper_Final_Spreads.pdf).



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29. Overlaying the transactions of the many participants in the opioid market is regulation and enforcement by the U.S. Drug Enforcement Administration (DEA), the U.S. Food and Drug Administration (FDA), and state pharmacy and licensing boards as well as administration of benefits by the Center for Medicare & Medicaid Services (CMS).<sup>24</sup> Opioids are regulated products subject to regular and continuous review by DEA, among other state oversight organizations (e.g., Prescription Drug Monitoring Programs (PDMP)).<sup>25</sup> Importantly, the volume of opioids is tracked by DEA through the Automated Reports and Consolidated Ordering System (ARCOS), and DEA sets production quotas for Schedule I and II product manufacturers each year.<sup>26</sup>

### III. Summary of Plaintiffs' Experts' Opinions

30. As shown in Exhibit 1 above, Plaintiffs' present their Economic Framework through the opinions of three experts. Their opinions are described below.

#### A. Professor Meredith Rosenthal

31. Professor Meredith Rosenthal's opinions establish the first stage of Plaintiffs' causation model, connecting Plaintiffs' marketing allegations to increased prescriptions and shipments of opioids, expressed as a function of morphine milligram equivalents (MMEs).<sup>27</sup>
32. Professor Rosenthal proposes two methodologies for estimating the share of opioid volumes due to Defendants' Alleged Conduct: a direct approach and an indirect approach.
33. The direct model attempts to assess the causal effect of Defendant manufacturer marketing (measured as detailing contacts based on physician survey data) on the volume of opioid

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<sup>24</sup> See, e.g., U.S. Food and Drug Administration, "Drugs," available at <https://www.fda.gov/drugs>; U.S. Drug Enforcement Administration, "Mission," available at <https://www.dea.gov/mission>; Centers for Medicare and Medicaid Services, "History," available at <https://www.cms.gov/About-CMS/Agency-Information/History/index.html>; Deposition of Eric Griffin, *In re National Prescription Opiate Litigation* (Jan. 23, 2019), at 70:20-73:7 ("Griffin Deposition"). See also, Rosenthal Report, at ¶¶ 18-22

<sup>25</sup> See, e.g., U.S. Department of Justice Drug Enforcement Administration Diversion Control Division, "ARCOS Retail Drug Summary Reports," available at [https://www.deadiversion.usdoj.gov/arcos/retail\\_drug\\_summary/](https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/); Griffin Deposition, at pp. 76-84.

<sup>26</sup> See U.S. Department of Justice Drug Enforcement Administration Diversion Control Division, "Quota Applications," available at [https://www.deadiversion.usdoj.gov/quotas/quota\\_apps.htm](https://www.deadiversion.usdoj.gov/quotas/quota_apps.htm); U.S. Department of Justice Drug Enforcement Administration Diversion Control Division, "ARCOS Retail Drug Summary Reports," available at [https://www.deadiversion.usdoj.gov/arcos/retail\\_drug\\_summary/](https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/).

<sup>27</sup> See Rosenthal Report, at ¶ 8.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

prescriptions dispensed at retail outlets (measured as the total opioid MMEs).<sup>28</sup> Notably, Professor Rosenthal makes no attempt to examine the content of any of the underlying marketing messages by any Defendant, instead basing her entire model off an assumption from counsel that Defendant detailing contacts were “unlawful.” From this direct approach, Professor Rosenthal concludes that [REDACTED] of total opioid MMEs, nationally, between 1995 and 2018 are due to Defendant manufacturers’ Alleged Conduct.<sup>29</sup> Additionally, Professor Rosenthal’s direct approach presents the only attempt by Plaintiffs’ Economics Experts to address alternative assumptions regarding liability among Defendants for the marketing Alleged Conduct.<sup>30</sup>

34. The indirect model attempts to account for demographic, economic and health factors related to prescription opioid shipments (measured as opioid MMEs per capita per day) in a baseline period (1997) and uses this relationship to attribute the remaining unexplained portion of shipments in subsequent periods to Defendants’ Alleged Conduct (i.e. a residual analysis).<sup>31</sup> This methodology assumes the relationship between the explanatory variables and opioid MMEs per capita per day in 1997 would have been constant in the but-for world from 1998 through 2016. From this indirect approach, Professor Rosenthal concludes that [REDACTED] of opioid MMEs is not explained by the chosen demographic, economic, and health factors and, therefore, is entirely attributed to Defendants’ Alleged Conduct, which she was instructed by counsel to assume was “unlawful.”<sup>32</sup>
35. Additionally, Professor Rosenthal incorporates assumptions provided by clinical experts into a simulation model to test the hypothesis that the growth in opioid shipments is due to growth

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<sup>28</sup> See Rosenthal Report, at ¶ 49.

<sup>29</sup> See Rosenthal Report, at p. 51, Table 2.

<sup>30</sup> See Rosenthal Report and Errata of Expert Report of Professor Meredith Rosenthal, *In Re National Prescription Opiate Litigation* (May 2, 2019) (“Rosenthal Report Errata”), at ¶ 76 and Table 3. See also, Rosenthal Deposition Vol. 1, 81:8-81:15, 164:10-164:17, 200:19-201:11, 434:2-434:12.

<sup>31</sup> See Rosenthal Report, at ¶ 79. Professor David Cutler acknowledges crucial limitations of residual analysis, “The indirect regression attributes the entirety of unexplained opioid-related mortality to shipments. To the extent that other factors not modelled in the “baseline” regression contributed to increases in opioid mortality, the indirect approach has the potential to overstate the impact of defendants’ actions.” See Cutler Report, at fn 53.

<sup>32</sup> See Rosenthal Report, at ¶ 79 and Table 5.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

in the treatment of previously under-treated pain or growth in the amount of opioids used to properly treat pain.<sup>33</sup>

36. She concludes (1) the promotion of pharmaceuticals increases their sales, (2) the combined effect of the Defendant manufacturers' promotion was a substantial contributing factor to the increase in use of prescription opioids in the Bellwether communities, (3) [REDACTED] of MMEs during the period of her analysis were caused by Defendant manufacturers' promotion, and (4) her methodology can be used to calculate the number of additional prescriptions caused by the promotion of any combination of Defendants.<sup>34</sup>

**B. Professor David Cutler**

37. Professor David Cutler incorporates Professor Rosenthal's estimates of the share of prescription opioid shipments that are attributable to Defendant manufacturers' Alleged Conduct into the second stage of Plaintiffs' economic framework for damages, which connects increased shipments to increased harms.<sup>35</sup> Professor Cutler's assignment is to determine, for specific administrative divisions of the Bellwether municipalities, whether increased shipments of prescription opioids since 1995 contributed to harms that resulted in costs faced by the divisions and, if so, the size of these effects and percentage attributable to shipments for which Defendants are responsible.<sup>36</sup>
38. Professor Cutler presents a three-step methodology for estimating the share of harm attributable to Defendants' Alleged Conduct. The first step estimates the share of harms attributable to opioids for five divisions: (1) criminal activity, (2) addiction and mental health activity, (3) children and family services, (4) juvenile court activity, and (5) medical examiner activity.
39. Professor Cutler's second step estimates the share of harms attributable to Defendants' Alleged Conduct based on the impact of excess shipments on opioid-related harm (mortality

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<sup>33</sup> See Rosenthal Report, at ¶¶ 90-91. Professor Rosenthal also presents a "thought experiment", in which her analysis performs the function of a calculator using assumptions provided by other Plaintiff experts. There is a clear dispute over the definition of the medical necessity of prescribed opioids, and her analysis fails to address the controversy analytically. It provides no sound economic basis to draw conclusions regarding causality or damages in this matter.

<sup>34</sup> See Rosenthal Report, at ¶ 11.

<sup>35</sup> See Cutler Report, at ¶ 9.

<sup>36</sup> See Cutler Report, at ¶ 10.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

due to opioid overdose). He uses a direct model to estimate the relationship between shipments (MMEs per capita per day) and opioid-related harms for 2006 to 2010. He also uses an indirect model to estimate the portion of harms due to licit and illicit opioids, not explained by economic, demographic, and health factors. Both approaches rely on Professor Rosenthal's results to estimate the percent of shipments attributable to Defendants' Alleged Conduct.

40. To calculate the final share of harms attributable to Defendants' Alleged Conduct, Professor Cutler provides two approaches for integrating the percent impact due to opioid shipments and the percent of opioid shipments attributable to Defendants' Alleged Conduct.<sup>37</sup> Approach 1 combines his direct and indirect model results to estimate the share of licit and illicit opioid mortality, respectively, attributable to shipments. Approach 2 relies entirely on his indirect model to estimate the share of harms as the increase in any opioid-related mortality that cannot be explained by changes in economic and demographic factors.
41. In the final step, Professor Cutler incorporates his estimated impact of opioid shipments on mortality with the share of each county's harm attributable to opioids calculated in his first step.<sup>38</sup> Although Professor Cutler considers a number of harms (e.g., crime and child removals), he uses his impact results for mortality as a proxy for the impact results of the non-mortality harms.
42. He reaches the following conclusions: (1) the increase in prescription opioid shipments since 1995 has contributed to harms, (2) the percentage increase in harms attributable to shipments can be estimated, (3) the percentage of harms attributable to Defendants' Alleged Conduct can be estimated by incorporating results from Professor Rosenthal's analysis, (4) his analysis is confirmed by a supplementary analysis of the direct effect of prescription opioid shipments on crime, and (5) his methodology can incorporate varying inputs.<sup>39</sup>

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<sup>37</sup> Share of opioid shipments attributable to Defendants' Alleged Conduct is based on results from Professor Rosenthal's direct model. *See* Rosenthal Report, at p. 51, Table 2. Professor Cutler's appendices present estimated harms due to all shipments and estimated harms due to Distributor Defendants' Alleged Conduct. *See* Cutler Report, Appendices III.I-J.

<sup>38</sup> Professor Cutler presents results for both Approach 1 and Approach 2, *See* Cutler Report, at pp. 70-71, Tables III.13-14

<sup>39</sup> *See* Cutler Report, at ¶ 11.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**C. Professor Thomas McGuire**

43. Professor Thomas McGuire incorporates Professor Cutler’s estimates of the share of harms that is attributable to Defendants’ Alleged Conduct into the third stage of Plaintiffs’ economic framework for damages, which connects increased harms to increased costs to the Bellwether municipalities.<sup>40</sup> Professor McGuire’s assignment is to determine whether the share of Bellwether municipality costs attributable to Defendants’ Alleged Conduct can be estimated in total as well as broken out by each municipality and budgetary component and, if so, the divisions affected and the amount of the costs.<sup>41</sup>
44. Professor McGuire’s analysis is “based on the view that governments allocate resources across its activities to maximize the welfare of its citizens subject to the constraints imposed by tax revenue and funds available through intergovernmental transfers”.<sup>42</sup> This opportunity-cost framework allows Professor McGuire to assume that “[g]overnments maximize the welfare of their constituents when resources are allocated to their most highly valued use, leading to a budgetary allocation in which the social value of an additional dollar is equal across services”. Therefore, under Professor McGuire’s assumption that the Bellwether governments are efficient, at full capacity, and maximize the welfare of the citizens, “the cost to a government of spending on one service is measured by the spending on that service, since that spending could have been devoted to other uses.”<sup>43</sup>
45. Professor McGuire’s resulting damages estimation is comprised of three parts: “(i) identification of certain Bellwether divisions affected by the opioid crisis and the total costs incurred by those divisions; (ii) identification of costs in the relevant divisions that address the relevant harms; and (iii) the identification of the share of harm attributable to defendants’ misconduct.”<sup>44</sup>
46. Professor McGuire identifies 19 divisions within the Bellwether governments that provided services related to (1) criminal activities; (2) child services; or (3) public health

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<sup>40</sup> See McGuire Damages Report, at ¶ 18.

<sup>41</sup> See McGuire Damages Report, at ¶ 7.

<sup>42</sup> See McGuire Damages Report, at ¶ 22.

<sup>43</sup> See McGuire Damages Report, at ¶ 23.

<sup>44</sup> See McGuire Damages Report, at ¶ 39.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

- initiatives.<sup>45</sup> Professor McGuire reviews budget, expenditure information, and activities from the Bellwether governments to identify divisions he claims are most affected by the opioid crisis.
47. Professor McGuire manually reviews the descriptions of relevant division expenditure line-items and categorizes them into “variable” costs that include: 1) salaries and benefits (i.e. compensation costs) and 2) non-compensation costs. He categorizes “fixed” costs as unaffected costs that do not vary in response to changes in the services provided.<sup>46</sup>
48. The final element of Professor McGuire’s framework - the share of harms attributable to Defendants’ Alleged Conduct – is presented entirely in the Professor Cutler’s report.<sup>47</sup> Professor McGuire does not offer any opinion related to causal relationship between Defendants’ Alleged Conduct and the costs incurred by the Bellwether governments.<sup>48</sup> Instead, Professor McGuire incorporates the analysis and results of Professor Cutler into his calculation of harm attributable to Defendants’ Alleged Conduct by applying Professor Cutler’s result to the variable costs described above. Professor McGuire calculates damages using the two approaches for the share of harms due to Defendant Alleged Conduct, presented in Professor Cutler’s report.<sup>49</sup>
49. He concludes the following: (1) the economic framework for damages presented by Plaintiffs experts is an economically appropriate approach for identifying costs due to Defendants’ Alleged Conduct,<sup>50</sup> (2) divisions affected by the opioid epidemic can be identified for each Bellwether municipality,<sup>51</sup> (3) variable costs for these divisions that were

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<sup>45</sup> See McGuire Damages Report, at ¶ 51. The Cuyahoga County divisions include: The Alcohol, Drug Addiction and Mental Health Services (ADAMHS) Board, The Division of Children and Family Services (DCFS), The Sheriff’s Office, The County Jail, The Office of Medical Examiner, The Office of Prosecutor, The Office of Public Defender, The Court of Common Pleas, and The Juvenile Court. (See McGuire Damages Report, at p. 31, Table IV.3.) The Summit County divisions include: The Alcohol, Drug Addiction, and Mental Health Services Board (ADM Board), The Children Services Board, The Sheriff’s Office, The County Jail, The Alternative Corrections program, The Medical Examiner, The Prosecutor, The Court of Common Pleas, The Adult Probation Department, and The Juvenile Court. (See McGuire Damages Report, at p. 33, Table IV.4.)

<sup>46</sup> See McGuire Damages Report, at ¶¶ 10 and 59.

<sup>47</sup> See McGuire Damages Report, at ¶ 72.

<sup>48</sup> See Deposition of Thomas G. McGuire, Ph.D., Volume I, April 23, 2019 (“McGuire Deposition Vol. 1”), p. 210:3-11.

<sup>49</sup> See McGuire Damages Report, at ¶ 72.

<sup>50</sup> See McGuire Damages Report, at ¶ 8.

<sup>51</sup> See McGuire Damages Report, at ¶ 9.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

affected by the opioid epidemic can be identified and separated from fixed costs,<sup>52</sup> and (4) by applying Professor Cutler's estimates of the percent of harms attributable to Defendants' Alleged Conduct, the identified affected costs yield damages estimates between \$194.4 and \$223.4 million between 2006 and 2018.<sup>53</sup>

50. In a separate report, Professor McGuire presents an analysis of the value of past externalities from opioid shipments that he proffers as related to alleged public nuisances from opioid shipments. Similar to his Bellwether Damages report, he relies on the work of Professors Rosenthal and Cutler for the causal connections between opioid shipments and alleged harms in The Bellwethers. I note however, that his methodology measures the past or sunk cost of these externalities and he does not provide an opinion about the value, if any, of the future externalities potentially avoided by relevant abatement activities. As such, Professor McGuire's analysis is not an examination of the asserted externalities, if any, that might be relevant to determining whether abatement costs are less than the value of the alleged nuisances avoided.

#### **IV. Expert Report of Professor Rosenthal**

51. Professor's Rosenthal's analysis primarily relies on IQVIA data in an attempt to show a causal relationship between Defendants' marketing (as measured by detailing contacts) and prescriptions of opioids. There are a number of serious issues with her assumptions, methodology, and conclusions that I investigate and evaluate below. Overall, her general approach is improperly dependent on models designed to simply fit data that is pooled across products and manufacturers. Her results fail to show reliable relationships that are also consistent with the underlying theories proffered by Plaintiffs and she fails to consider the substantial uncertainty of her projections which extend for nearly two decades from her baseline periods. As applied, her direct model does not isolate the effect of any particular manufacturer. The aggregate approach of the direct model cannot isolate liability for any individual manufacturer. Specifically, her models do not establish that any Mallinckrodt marketing caused an increase in opioid volume.

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<sup>52</sup> See McGuire Damages Report, at ¶ 10.

<sup>53</sup> See McGuire Damages Report, at ¶ 11.



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**A. Professor Rosenthal’s analysis fails to capture certain important drivers of physician prescribing behavior and assumes Defendant manufacturer detailing is unlawful without analyzing the messaging content**

52. Professor Rosenthal’s direct model uses survey data to approximate a number of manufacturer detailing contacts to purportedly measure the causal effect of marketing on the volume of total opioid prescriptions, expressed as MMEs.<sup>54</sup> Professor Rosenthal obtains the measure of manufacturer detailing contacts from IQVIA Integrated Promotional Service (IPS). This data source is derived from a purportedly nationally representative survey of office-based practices, and IQVIA projects the survey results to a larger universe of providers.<sup>55</sup>
53. Professor Rosenthal relies on Counsel for the assumption that the fact finder will determine that “all or virtually all promotion by the manufacturer Defendants from 1995 to the present was unlawful.”<sup>56</sup> Importantly, she treats detailing by non-defendant manufacturers and sometimes by Defendants as lawful without any further analysis of how, why, and when the marketing content of these contacts differed from her assumed unlawful contacts.<sup>57</sup> Her measure of conduct is strictly a count of contacts incapable of reflecting the type or content of promotion that the fact finder might determine unlawfully induces opioid prescriptions. Professor Rosenthal then uses the estimated relationship between manufacturer detailing and total opioid MMEs from her preferred direct model (Model B) to predict but-for levels of opioid MMEs by assuming that, in the but-for world, the count and pattern of contacts over time for all manufacturers would equal the count and pattern of the assumed lawful contacts. Professor Rosenthal estimates excess MMEs due to Defendants’ Alleged Conduct as the

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<sup>54</sup> See Rosenthal Report, at ¶¶ 7, 49, and 56.

<sup>55</sup> See Rosenthal Report, at ¶ 51. See e.g., Kornfield, Rachel, et al., “Promotion of Prescription Drugs to Consumers and Providers, 2001-2010,” *PLoS ONE* 8(3) (Mar. 4, 2013), at pp. 2-3.

<sup>56</sup> See Rosenthal Report, at ¶ 75; Rosenthal Deposition Vol. 1, 29:24-32:5.

<sup>57</sup> For some Defendant manufacturers, Professor Rosenthal assumes that unlawful detailing is limited to certain products (e.g., Mallinckrodt’s unlawful detailing is assumed to be detailing for Exalgo, Xartemis, and Anexsia). Therefore, any of the Defendant manufacturers’ detailing that is not related to those products is assumed to be lawful and included in the definition of the but-for level of detailing. Additionally, Professor Rosenthal also considers some detailing conducted by non-Defendants for Defendant products to be unlawful, and therefore, they are excluded from the but-for level of detailing. See Rosenthal Report, supporting materials.



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

difference between actual MMEs less predicted but-for MMEs without further analysis of the contact attributes, which of course can vary by type, length, and content.<sup>58</sup>

**1. Professor Rosenthal fails to account for the role of learned intermediary physicians and the variety of factors impacting physicians' prescribing decisions**

54. Professor Rosenthal relies on the expert report of Dr. Matthew Perri to support (1) her hypothesis that Defendant manufacturer marketing influenced providers to write opioid prescriptions and (2) her use of the number of provider detailing contacts to measure the effect of marketing.<sup>59</sup> Exhibit 6 displays the promotion ecosystem that Professor Rosenthal describes with reference to Dr. Perri's report and indicates the complexity of the hypothesized relationships at issue.<sup>60</sup> Despite acknowledging many factors in the posited "promotion ecosystem", Professor Rosenthal's models do not account for these influences. For example, although Professor Rosenthal attempts to establish the far-reaching effects of provider detailing by referencing Dr. Perri's statement that peer-to-peer marketing acts as a form of contagion,<sup>61</sup> the marketing measure in her regression analysis remains a count of detailing contacts only.

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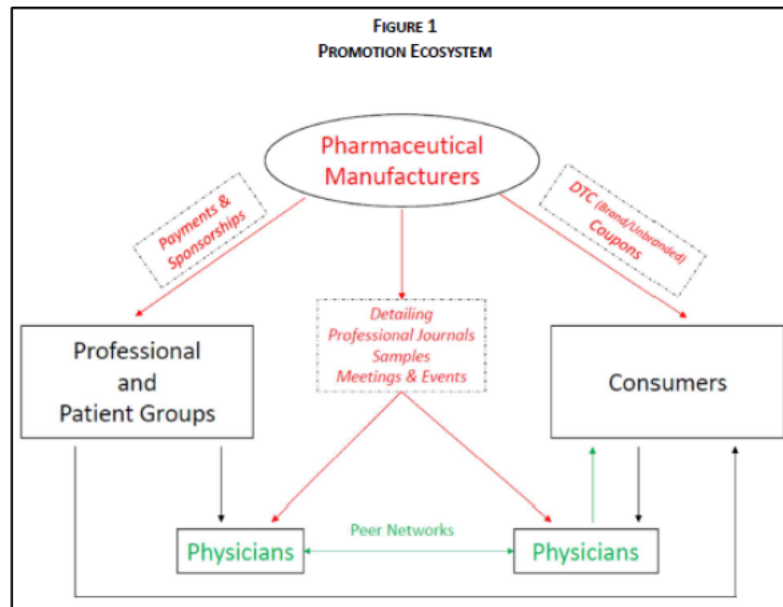
<sup>58</sup> See Rosenthal Report, at ¶ 75.

<sup>59</sup> See, e.g., Rosenthal Report, at ¶¶ 25, 30, 56, 57, 66, and fn 45; Rosenthal Deposition Vol. 1 186:1-186:21.

<sup>60</sup> See Rosenthal Report, at p. 19, Figure 1. Like Professor Rosenthal, Dr. Perri also assumes that "a group of other experts will be providing testimony" regarding whether the Defendants' marketing messages were false. See Deposition of Matthew Perri, III, BS Pharm, Ph.D., RPh, Vol. 1, *In Re National Prescription Opiate Litigation* (Apr. 23, 2019) ("Perri Deposition Vol. 1"), at 83:21-85:9.

<sup>61</sup> See Rosenthal Repot, at ¶ 25, citing Expert Report of Matthew Perri III, BS Pharm, PhD, RPh, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019) ("Perri Report"), at ¶ 69.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 6: Reproduction of Professor Rosenthal's Promotion Ecosystem<sup>62</sup>**

55. In addition, Professor Rosenthal's hypothesized causation theory is artificially focused on a one-directional communication between manufacturers and physicians. Her "ecosystem" does not recognize the flow of information from physicians to manufacturers that occur routinely in the healthcare industry (e.g., physician medical research, Phase IV drug trials).<sup>63</sup> It also does not incorporate potential mitigating factors stemming from the provider's (1) role as a learned intermediary with the ability to discern between scientific evidence and promotional information, (2) ability to make prescribing decisions based on evidence and what is medically necessary for the patient's conditions, needs, and expectations, and (3) access to information to consider the relative availability and efficacy of alternative treatments.
56. These factors are important to understand if and how easily providers could be influenced by the Alleged Conduct and induced to prescribe medically unnecessary or inappropriate opioid therapies. As Professor Rosenthal notes, studies in other contexts suggest that it is

<sup>62</sup> See Rosenthal Report, at p. 19, Figure 1.

<sup>63</sup> See, e.g., Zhang X., Zhang Y., Ye X., Guo X., Zhang T., and He J., "Overview of phase IV clinical trials for postmarket drug safety surveillance: a status report from the ClinicalTrials.gov registry," (Nov. 23, 2016) doi: 10.1136/bmjopen-2015-010643. ClinicalTrials.gov records over 4500 phase IV trials conducted between 2004 and 2014. Physicians play an active role in adverse event monitoring in phase IV trials by filling out and submitting adverse event reports.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

difficult to determine whether physicians appropriately differentiate between scientific evidence and promotional information.<sup>64</sup> This statement, in itself, recognizes that some physicians *are* able to differentiate information. Specifically regarding opioids, there is information from healthcare surveys indicating that fentanyl prescribers, pharmacists, as well as patients reflected “generally high levels of knowledge regarding proper TIRF prescribing.”<sup>65</sup> Results like this support that prescriber and pharmacists have the knowledge required to act as appropriate gatekeepers for the use of opioids. Professor Rosenthal does not consider how the prescribers’ status as a learned intermediary or other similar countervailing factors affect Plaintiffs’ theory of marketing causality. Exhibit 7 presents a summary diagram of a number of theories that have been considered regarding influences and prescribing behavior.<sup>66</sup> Additionally, Dr. Perri recognizes a number of stakeholders who can impact prescribing; “drug utilization review board and pharmacy and therapeutics committee members, insurers and third-party payers, formulary managers, or pharmacy benefit managers.”<sup>67</sup> Many of these factors have nothing to do with the Alleged Conduct here and yet, were not addressed—much less adequately controlled for—in Professor Rosenthal’s analysis.

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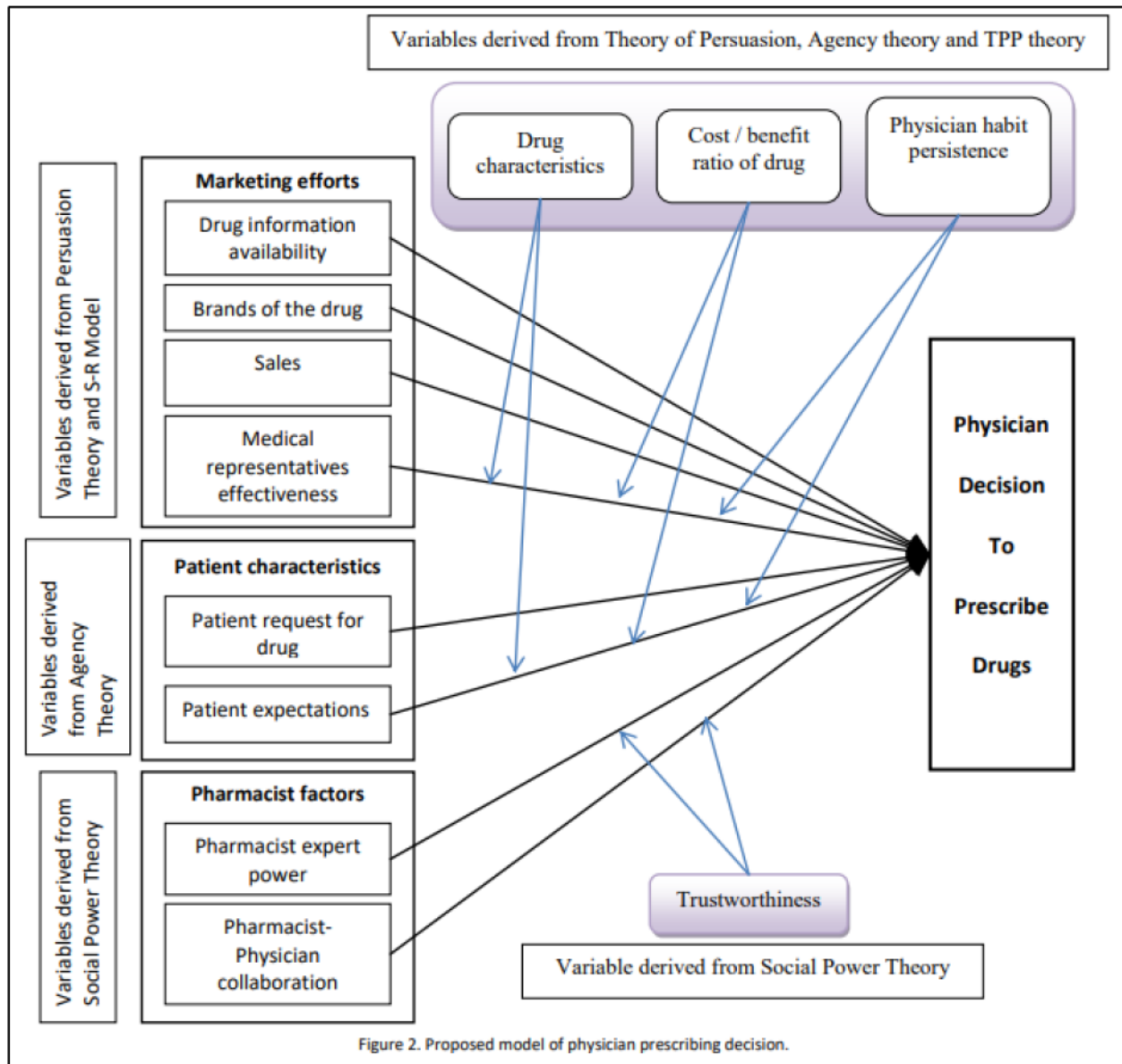
<sup>64</sup> See Rosenthal Report, at ¶ 29.

<sup>65</sup> See Rollman, Jeffrey Eric, et al., “Assessment of the FDA Risk Evaluation and Mitigation Strategy for Transmucosal Immediate-Release Fentanyl Products,” *Journal of the American Medical Association* 321, no. 7 (2019), at p. 684.

<sup>66</sup> See Murshid, Ali and Zurina Mohaidin, “Models and theories of prescribing decisions: A review and suggested a new model,” *Pharmacy Practice*, 2017 Apr-Jun 15(2):990, at p. 8, Figure 2.

<sup>67</sup> See Perri Report, at fn 39.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 7: Factors Influencing Physician Prescribing Behavior<sup>68</sup>**

**2. Professor Rosenthal's model relies on the number of manufacturer detailing contacts without evaluating the content of the messaging**

57. Professor Rosenthal is estimating the average effect of detailing contacts by both Defendant and non-defendant manufacturers on the volume of opioid MMEs.<sup>69</sup> She acknowledges that,

<sup>68</sup> See Murshid, Ali and Zurina Mohaidin, "Models and theories of prescribing decisions: A review and suggested new model," *Pharmacy Practice*, 2017 Apr-Jun 15(2):990, at p. 8, Figure 2.

<sup>69</sup> See, e.g., Deposition of Meredith Rosenthal, Ph.D., Vol. 1, *In Re National Prescription Opiate Litigation* (May 4, 2019), ("Rosenthal Deposition Vol. 1"), at 205:19-206:8.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

in the actual world, there is variation in messaging context and detailing contact effectiveness.<sup>70</sup> Nonetheless, she uses her estimated “average effect” and a subset of assumed “lawful” detailing contacts to predict opioid volume in the but-for world. Importantly, Professor Rosenthal is using the magnitude and temporal pattern of contacts by **non-defendants** to define the marketing of **all manufacturers**, but-for the Alleged Conduct. This assumes non-defendant contacts in the actual world would define total contacts in the but-for world by both Defendants and non-defendants combined. This is a significant and unsupported assumption.

58. From the IPS data, Professor Rosenthal obtains three pieces of information about the detailing contacts used in her direct model: (1) the associated manufacturer, (2) the product discussed, and (3) the month of contact. Based on instructions from Plaintiffs’ counsel, Professor Rosenthal’s treatment of detailing and its function in her model estimation assumes that all detailing contacts are considered equal across manufacturers and products.<sup>71</sup> In a given month, a detailing contact by Purdue for OxyContin is considered the same as a detailing contact by Mallinckrodt for Exalgo, and both are considered the same as a detailing contact by a non-defendant manufacturer. One detailing contact, however, might represent an interaction between a sales representative and a prescriber during which several pieces of detailed scientific and medical information for a specific opioid product were discussed, while another detailing contact might represent a simple inquiry as to the prescriber’s experience with a particular opioid. The type of content conveyed to a prescriber in the first scenario reasonably could have a different effect on prescribing decisions than the content conveyed in the second scenario.<sup>72</sup>
59. Professor Rosenthal has not attempted to analyze prescriber detailing content and provides no basis for determining which detailing contacts conveyed messaging associated with the Alleged Conduct. Mallinckrodt’s expert, Dr. Michael Weinberger, reviewed the content of

<sup>70</sup> See, e.g., Rosenthal Deposition Vol. 1, 197:4-197:11; Rosenthal Deposition Vol. 1, 205:23-205:25.

<sup>71</sup> Professor Rosenthal’s calculation of marketing stock as well as the three eras of “marketing effectiveness” in Models B and C allow for variation in the effectiveness of detailing contacts over time, but not variation in effectiveness due to message type, product, or source of the message.

<sup>72</sup> See, e.g., Gallan, A., “Factors that Influence Physicians’ Prescribing of Pharmaceuticals: A Literature Review,” *Journal of Pharmaceutical Marketing & Management*, (2004) 16(4) at p. 10, ¶ 2; Kappe, E. and Stefan Stremersch, “Drug Detailing and Doctors’ Prescription Decisions: The Role of Information Content in the Face of Competitive Entry,” *Marketing Science*, (Nov.-Dec. 2016) 35(6), at p. 931.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

Mallinckrodt's marketing materials (e.g., a sales tool used by sales representatives to describe potential Exalgo prescribing scenarios) and found that they were clinically accurate. Dr. Weinberger's findings illustrate that Professor Rosenthal cannot rely on Counsel to assume that all detailing contacts for certain Defendant manufacturer products were unlawful.

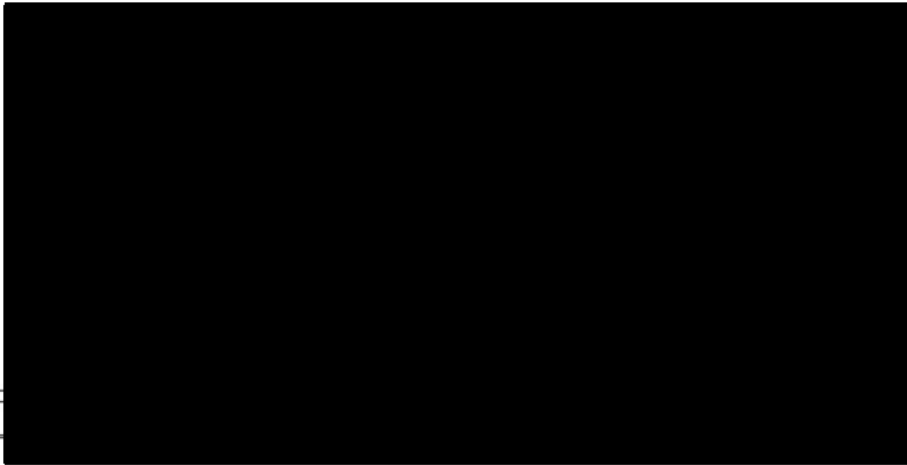
60. Since Professor Rosenthal's measure of manufacturer marketing does not capture the messaging content of the interaction, she cannot distinguish the impacts of detailing contacts that contained lawful marketing messages from those messages that Plaintiffs allege were unlawful. Thus, Professor Rosenthal's direct model is of no assistance to determine whether certain messages communicated during a Defendant manufacturer's detailing were unlawful, and whether those messages, in particular, caused an increase in prescriptions.
61. Moreover, Professor Rosenthal relies on Plaintiffs' Counsel to "assume in [her] but-for scenarios that the fact finder (judge or jury) finds that all or virtually all promotion by the manufacturer Defendants from 1995 to the present was unlawful."<sup>73</sup> She interprets this direction as a requirement that the but-for magnitude and temporal pattern of detailing for at-issue opioids is constrained to mimic the detailing by the non-defendants. This is neither a necessary condition for modeling the detailing in the but-for world, nor a reasonable one.
62. Exhibit 8 summarizes detailing contacts by manufacturer and Professor Rosenthal's lawful versus unlawful designation when defining the but-for world. Her methodology assumes that approximately [REDACTED] of detailing contacts would exist in the but-for world and the pattern of those contacts is fixed.

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<sup>73</sup> See Rosenthal Report, at ¶ 75; Rosenthal Deposition Vol. 1 at 81:8-81:15, 164:10-164:17, 200:19-201:11, and 434:2-434:12

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 8: Summary of Detailing Contacts by Manufacturer – 1995-2018**

	Total Detailing		Detailing Excluded from Rosenthal's But-For World	Detailing Included in Rosenthal's But-For World
	# of Contacts	% of Total	# of Contacts	# of Contacts
<i>Defendant</i>				
Actavis				
Dupont				
Endo Labs				
Insys Therapeutics				
Janssen				
Mallinckrodt				
Purdue				
Teva				
<i>Non-Defendants</i>				
Defendant Products				
Non-Defendant Products				
<b>Total</b>				

Source: IQVIA IPS (1995-2018); Rosenthal Report, Table 2 and supporting materials.

63. By treating the direction from Counsel as she did, Professor Rosenthal has avoided answering the critical question: what would be the level and pattern of detailing in the but-for world and how effective would it be regarding opioid volume? As noted by Dr. Perri, the answer requires consideration of many factors:<sup>74</sup>

Q. When you say in Paragraph 16 that you're examining marketing in a real world context, what does that mean?

A. Well, you know, I think with regard to opioids in particular, to look at the marketing and not consider what was happening at a societal level at any point during the marketing of the opioids would be taking it out of its real world context; for example, omitting that there were, at various places along the way, growing awareness of potential problems with opioids, the rapid expansion of the marketplace, so any number of issues that would come up, the numbers of competitors in the marketplace, the numbers of competing alternative goods or drugs that might be used.

<sup>74</sup> See Perri Deposition Vol. 1, at 79:17-80:16.



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

So there are a number of factors that create the real world context. For example, the size of a particular sales force is a real world context... I would think that the real world context would necessarily include changing paradigms about treatment of pain.

64. Importantly, Professor Rosenthal's aggregation of detailing improperly separates specific product marketing from sales of that product. This is an unreasonable treatment because it essentially implies no relationship between marketing messages and specific product sales. Professor Rosenthal's approach indicates that she understands there is a relationship for marketing effectiveness not due to the Alleged Conduct but her simplification to identify but-for conditions disregards the underlying economics. It does so by concealing the relationship between specific product volumes and their respective detailing. This is a more general problem of her econometric model and the specification of how detailing relates to opioid volume that I address more fully below.
65. As an example of the potential inconsistencies in detailing patterns across Defendants, according to the IPS data, Mallinckrodt conducted only [REDACTED] of all opioid detailing contacts (see Exhibit 8). I understand from Counsel that Mallinckrodt marketed Exalgo and Xartemis after 2010, during which the volume of opioid MMEs in the market was generally declining. These two products only account for [REDACTED] of the volume of opioid MMEs.<sup>75</sup> Their small share of the national opioid market is further illustrated in Exhibit 9. Specifically, regarding the Bellwethers, Exalgo and Xartemis are a small volume of prescriptions and opioid MMEs, as shown in Exhibit 10. Professor Rosenthal is aggregating Mallinckrodt's marketing and product MMEs with other opioid manufacturers and any assessment of aggregate causation is unlikely to be representative of an individual manufacturer, such as Mallinckrodt.

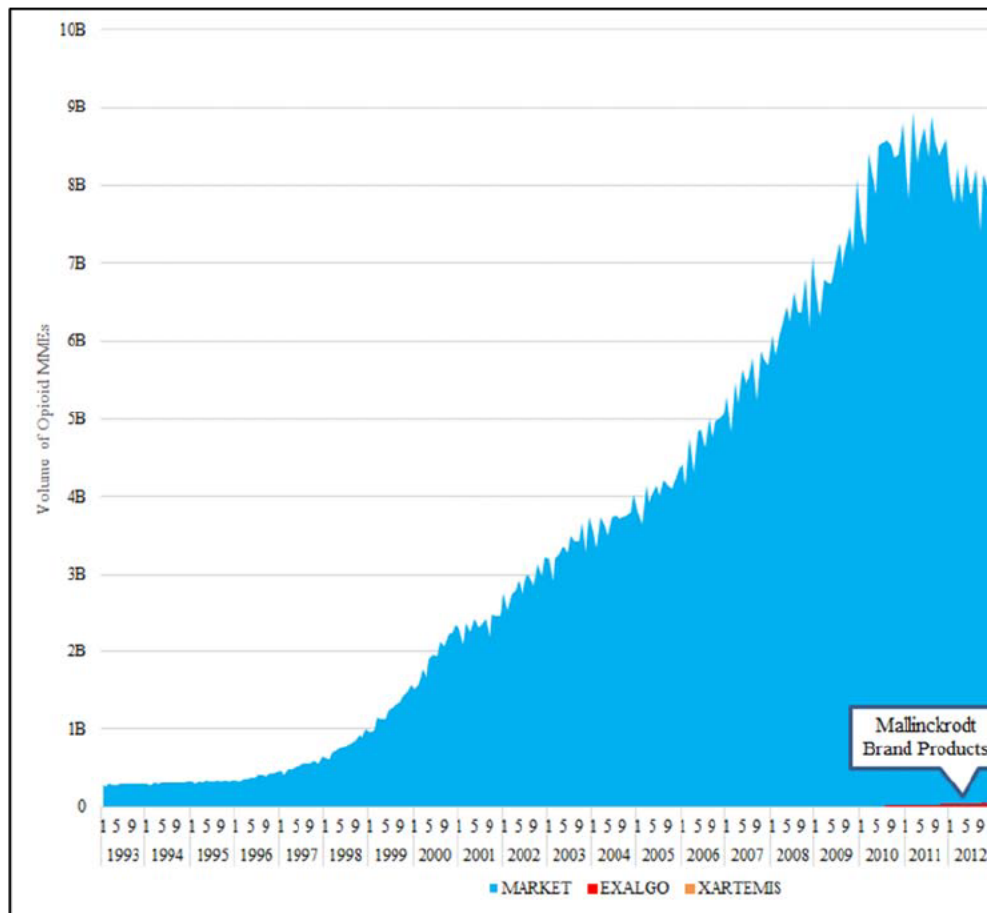
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<sup>75</sup> See Rosenthal Report, at Table C.1.



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 9: Exalgo and Xartemis MMEs versus Total Opioid MMEs**



**Source:** IQVIA NPA; Rosenthal Report, supporting materials.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 10: Exalgo and Xartemis Rx and MMEs in the Bellwethers**

Year	Prescriptions of At-Issue Opioid Products			MMEs of At-Issue Opioid Products		
	All Products	Exalgo	Exalgo as % of All Products	All Products	Exalgo	Exalgo as % of All Products
1997	1,023,206	0	0.0%	582,985,313	0	0.0%
1998	1,046,604	0	0.0%	598,523,657	0	0.0%
1999	1,132,734	0	0.0%	677,332,567	0	0.0%
2000	1,219,569	0	0.0%	770,834,497	0	0.0%
2001	1,286,294	0	0.0%	844,922,877	0	0.0%
2002	1,391,452	0	0.0%	932,877,950	0	0.0%
2003	1,465,274	0	0.0%	1,041,765,895	0	0.0%
2004	1,532,571	0	0.0%	1,106,767,995	0	0.0%
2005	1,609,064	0	0.0%	1,186,463,053	0	0.0%
2006	1,713,073	0	0.0%	1,310,481,662	0	0.0%
2007	1,781,714	0	0.0%	1,363,123,066	0	0.0%
2008	2,007,622	0	0.0%	1,567,872,130	0	0.0%
2009	2,097,892	0	0.0%	1,650,304,091	0	0.0%
2010	2,171,968	515	0.0%	1,770,747,429	927,082	0.1%
2011	2,191,738	1,580	0.1%	1,759,909,663	2,927,680	0.2%
2012	2,082,355	2,298	0.1%	1,595,874,301	5,223,737	0.3%
2013						
2014						
2015						
2016						
2017						
1997 to 2017						

**Source:** IQVIA/IMS Xponent data (ALLERGAN\_MDL\_02485011, ALLERGAN\_MDL\_02949563, ALLERGAN\_MDL\_03281086).

Year	Prescriptions of At-Issue Opioid Products			MMEs of At-Issue Opioid Products		
	All Products	Xartemis	Xartemis as % of All Products	All Products	Xartemis	Xartemis as % of All Products
1997	1,023,206	0	0.0%	582,985,313	0	0.0%
1998	1,046,604	0	0.0%	598,523,657	0	0.0%
1999	1,132,734	0	0.0%	677,332,567	0	0.0%
2000	1,219,569	0	0.0%	770,834,497	0	0.0%
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2002	1,391,452	0	0.0%	932,877,950	0	0.0%
2003	1,465,274	0	0.0%	1,041,765,895	0	0.0%
2004	1,532,571	0	0.0%	1,106,767,995	0	0.0%
2005	1,609,064	0	0.0%	1,186,463,053	0	0.0%
2006	1,713,073	0	0.0%	1,310,481,662	0	0.0%
2007	1,781,714	0	0.0%	1,363,123,066	0	0.0%
2008	2,007,622	0	0.0%	1,567,872,130	0	0.0%
2009	2,097,892	0	0.0%	1,650,304,091	0	0.0%
2010	2,171,968	0	0.0%	1,770,747,429	0	0.0%
2011	2,191,738	0	0.0%	1,759,909,663	0	0.0%
2012	2,082,355	0	0.0%	1,595,874,301	0	0.0%
2013						
2014						
2015						
2016						
2017						
1997 to 2017						

**Source:** IQVIA/IMS Xponent data (ALLERGAN\_MDL\_02485011, ALLERGAN\_MDL\_02949563, ALLERGAN\_MDL\_03281086).

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**B. Professor Rosenthal's direct model suffers from a number of problems related to her model specification and estimation**

**1. Professor Rosenthal's adjusts her model to fit the underlying data and does so by assuming that marketing effectiveness varies by three eras without economic justification**

66. Professor Rosenthal uses her measure of detailing to specify a “stock of promotion” variable that she proffers as the causal link between marketing and opioid prescriptions. Professor Rosenthal proffers that opioid prescriptions in a particular month are driven not only by contemporaneous detailing, but by the cumulative detailing efforts in all prior months (the “stock of promotion”). Professor Rosenthal allows the cumulative detailing efforts from all prior months to accumulate. Then she applies a particular rate to the accumulated stock of promotion, which she calls the “depreciation rate.”<sup>76</sup>
67. An example helps to illustrate the implications of Professor Rosenthal's methodology. Using the depreciation rate in her preferred Model B (which is negative, meaning that it is really an *appreciation* rate and the impact gets larger over time), **one** contact performed in January 1993 translates to a stock of promotion of **7.65** by May 2018 (the end of Professor Rosenthal's direct model analysis). Thus, Professor Rosenthal's “depreciation rate” is actually an appreciation rate which results in the “stock of promotion” growing over time.
68. Professor Rosenthal's Model A uses the stock of promotion and an aggregate price index to estimate the relationship between marketing and opioid prescriptions and predict total opioid MME volume in the but-for world. The predicted values of this simple model exhibit an almost linear trend between 1995 and 2018. They are substantially dissimilar from the non-linear trend exhibited by actual total opioid MME volume (see Exhibit 12 below). Model A estimates a positive, but not statistically significant, monthly depreciation rate (0.05%) and predicts illogical but-for prescription values that are negative after 2014.<sup>77</sup>
69. Rather than considering omitted variables that could address her poorly fitting Model A, Professor Rosenthal hypothesizes that the effect of the stock of promotion on total opioid MMEs changes over time (i.e. “the effectiveness of promotion” changes over time).<sup>78</sup>

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<sup>76</sup> See Rosenthal Report, at ¶ 62.

<sup>77</sup> See Rosenthal Report, at Attachment D, Table D.1 and Figure D.1.

<sup>78</sup> See Rosenthal Report, at ¶ 71.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

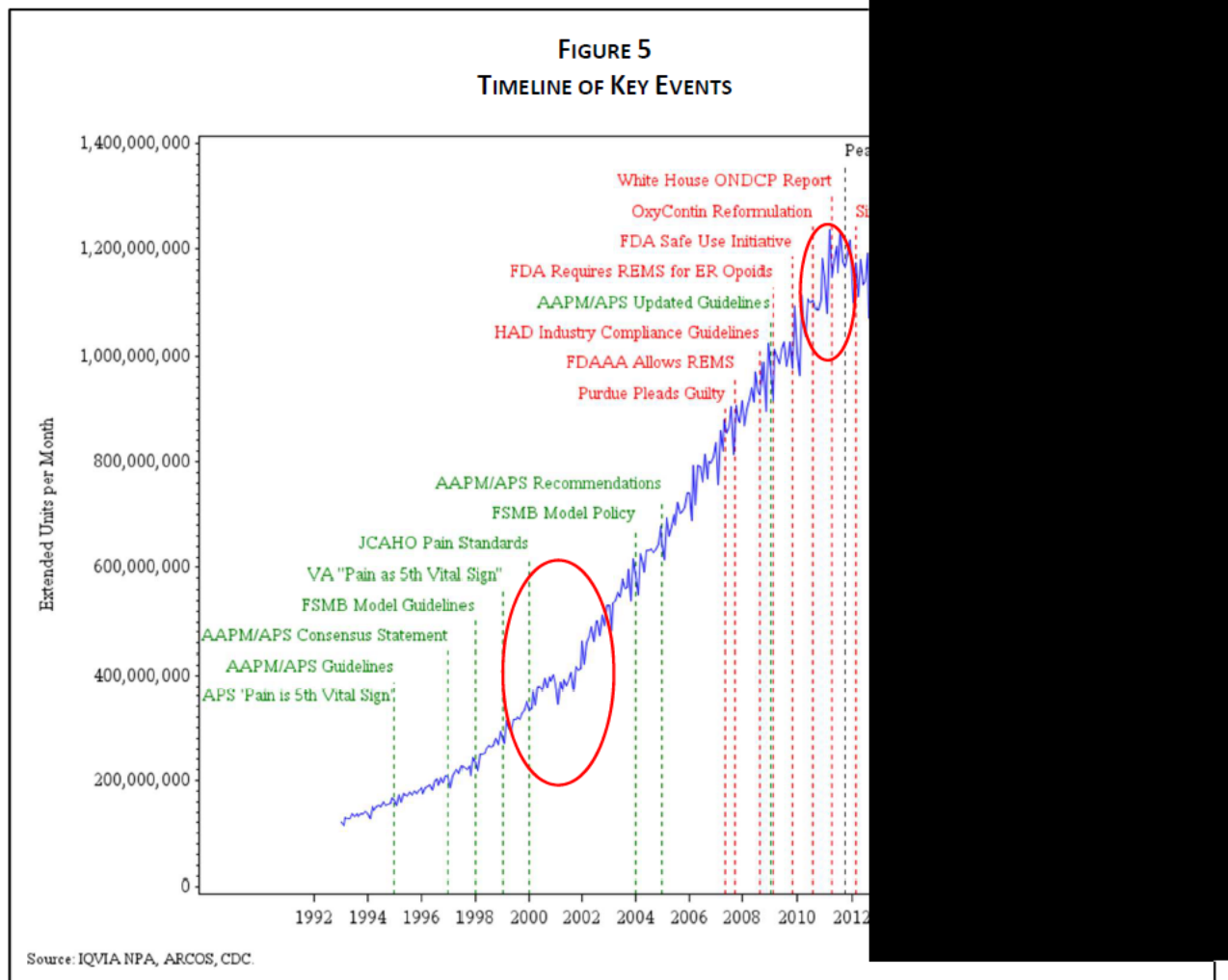
Additionally, rather than grounding her hypothesis of changing detailing effectiveness in economic theory (e.g., specific events during the timeline of the opioid epidemic that could have changed the effectiveness of detailing), Professor Rosenthal defines the three eras of detailing effectiveness by hypothesizing there are two periods in which the relationship between quantity and marketing changed. The first period is between January 1999 and January 2003 and the second period is between January 2010 and December 2011. Her preferred model (Model B, shown in Exhibit 13 below) is chosen by examining all combinations of months that fall within her hypothesized periods and selecting the model with the “best fit,” one with March 2002 and August 2010 “turning points”.<sup>79</sup> Importantly, the methodology for the selection of the turning points forces the definition of the three eras of marketing effectiveness to be a function of the model’s specifications (i.e. changing the explanatory variables of the direct model can impact the selected turning points).

70. Professor Rosenthal does not provide a defensible economic rationale for the hypothesized periods, circled in Exhibit 11. The first estimated turning point occurs in March 2002, which does not coincide with an important event in the timeline of the opioid epidemic shown in Exhibit 11. This decision forces the model to reflect a stronger relationship between marketing and opioid prescriptions than may exist in the actual world.

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<sup>79</sup> See Rosenthal Report, at Attachment D, pp. D3-D5. The dates with the best fit are defined as the combination with the highest Wald statistic.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 11: Professor Rosenthal's Figure 5 with Highlighted Periods<sup>80</sup>**

71. By changing the direct model specification to estimate the effect of the stock of promotion on total opioid MME volume separately for each of the three eras, Professor Rosenthal's Model B (which she ultimately selects as her preferred model) estimates a negative monthly depreciation rate of - 0.67%.<sup>81</sup> To explain the counterintuitive negative depreciation rate (which is in fact an appreciation rate), Professor Rosenthal asserts that a negative rate is reasonable for an "addictive product like opioids."<sup>82</sup> However, her explanation is insufficient to understand the variation in the depreciation rates between Models A (0.05%) and B (-

<sup>80</sup> See Rosenthal Report, at p. 41, Figure 5.

<sup>81</sup> See Rosenthal Report, at p. 47, Table 1.

<sup>82</sup> See Rosenthal Report, at ¶ 72.

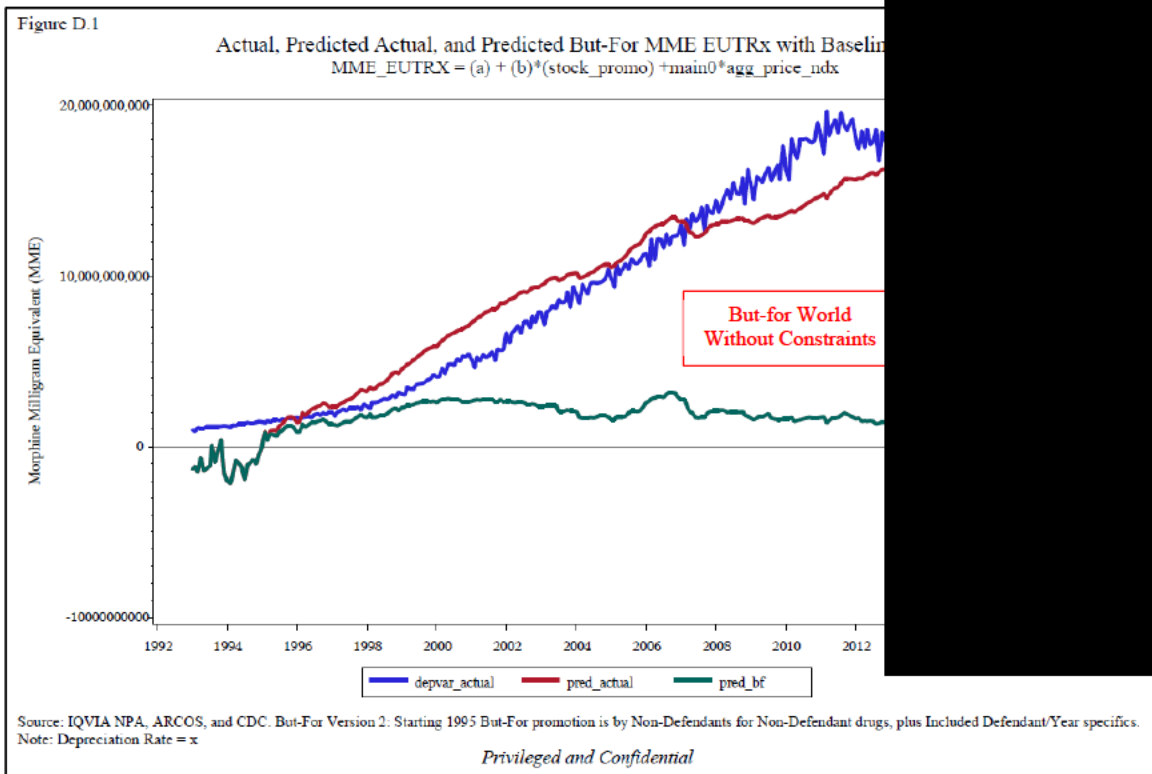
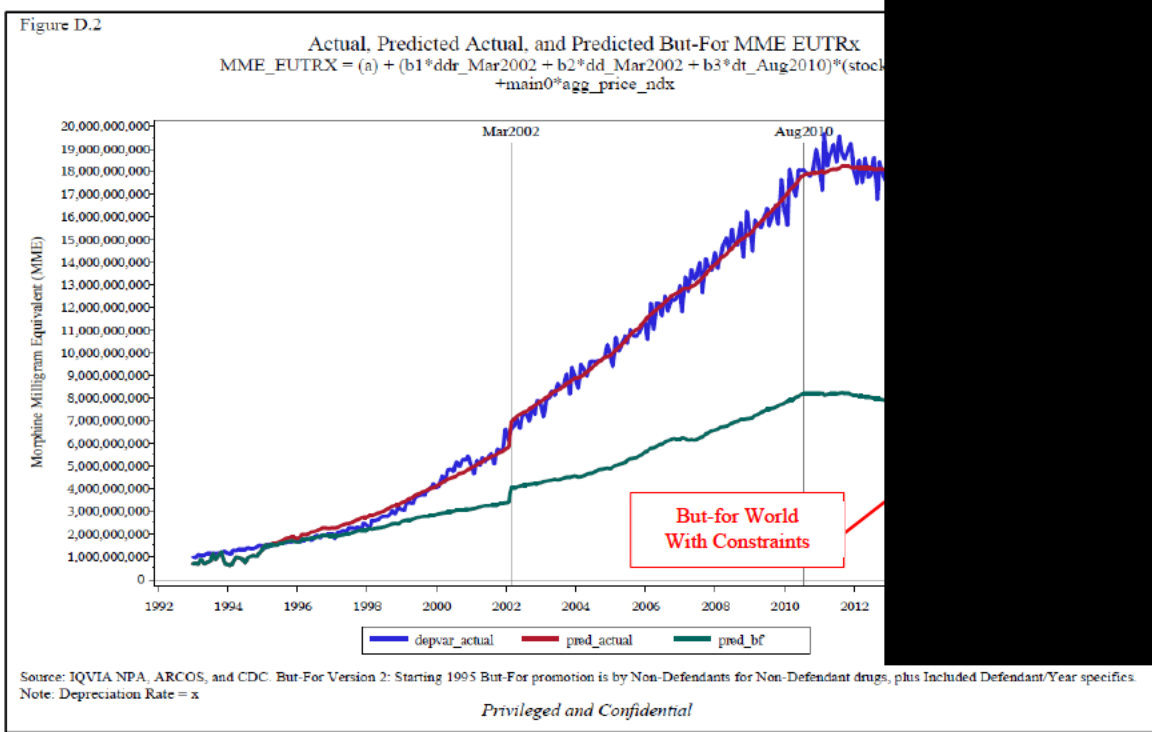
HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

- 0.67%) and the observed change in sign because both models estimate the relationship between detailing and sales of the same opioid products.
72. Although not specifically acknowledged by Professor Rosenthal, implementing the specification that detailing effectiveness varies during three eras between 1993 and 2018 requires that marketing effectiveness varies by the same three eras in her but-for world predictions.<sup>83</sup> Importantly, the stock of promotion is the explanatory variable that Professor Rosenthal replaces with “lawful” detailing when estimating the level of opioid MME volume in the but-for world. Therefore, Professor Rosenthal assumes that, in the but-for world, the stock of promotion would exhibit the same relationship to prescribing as in the actual world (i.e. would vary in effectiveness by the same three eras).
73. Professor Rosenthal does not provide an economic foundation or rationale for this assumption. She does not appear to consider that, in the but-for world, the opioid market likely would exhibit different marketing patterns that impact the eras of marketing effectiveness (e.g., different levels of marketing or timing of certain events). If it is unrealistic that marketing effectiveness varies by the same three eras in the but-for world (i.e. the turning points in the actual world are not the same as the but-for world), then only Professor Rosenthal’s Model A is presumably reasonable. It is clear, however, that Model A is not sufficient to estimate the but-for world. Exhibit 12 illustrates the but-for world using Model A without the constraints of the three eras of detailing effectiveness, and Exhibit 13 illustrates the but-for world using Model B with the three eras of detailing effectiveness. Model A produces an unrealistic but-for world with negative predicted opioid prescriptions, and only with Model B’s selected “turning points” does Professor Rosenthal achieve positive predicted opioid prescriptions.

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<sup>83</sup> See Rosenthal Report, at p. 47, Table 1.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 12: Professor Rosenthal's Model A, Figure D.1 Without But-for World Constraints<sup>84</sup>****Exhibit 13: Professor Rosenthal's Model B, Figure D.2 With But-for World Constraints<sup>85</sup>**



## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

74. Professor Rosenthal’s “direct model” is her basis to assess the causal effect of Defendant manufacturer marketing (measured as the number of detailing contacts) on the volume of opioid prescriptions dispensed at retail outlets (measured as the total opioid MMEs).<sup>86</sup> Instead of testing whether her model using the stock of promotion variable explains opioid volume, however, Professor Rosenthal specifies the three turning points in her model to fit the data. This produces contrived results and not an objective method of investigating her promotion theory. Nonetheless, from this direct approach, Professor Rosenthal concludes that [REDACTED] of total opioid MMEs, nationally, between 1995 and 2018 are due to the Alleged Conduct.<sup>87</sup>
75. Importantly, Professor Rosenthal’s direct approach presents the only attempt by Plaintiffs’ Economics Experts to apportion liability among Defendants.<sup>88</sup> Table 3 of Professor Rosenthal’s report demonstrates how her estimate of the share of “aggregate harm” changes based on varying assumptions of Defendant manufacturers’ liability. Her results indicate that if Mallinckrodt’s promotion were to be deemed lawful, excess opioid MMEs would only decrease by [REDACTED].<sup>89</sup> In other words, according to Professor Rosenthal’s own direct model, Mallinckrodt’s promotion accounts for a very small portion of “aggregate harm”—directly undercutting Plaintiffs’ allegation that Mallinckrodt caused a substantial portion of the alleged harm that forms the basis of this case.<sup>90</sup>
76. There are other technical problems with Professor Rosenthal’s direct model that render it unreliable for her purposes. Professor Rosenthal uses the direct model to show that “in economic terms there is a causal relationship between the Defendants’ promotion and prescriptions of opioids so that if the allegations of misconduct are proven true, impact can be found.”<sup>91</sup> She concludes that “Model B is a fair, accurate and econometrically sound method by which to estimate the relationship of the Defendants’ detailing of opioids on the

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<sup>84</sup> See Rosenthal Report, at Attachment D, Figure D.1.

<sup>85</sup> See Rosenthal Report, at Attachment D, Figure D.2.

<sup>86</sup> See Rosenthal Report, at ¶ 49.

<sup>87</sup> See Rosenthal Report, at p. 51, Table 2.

<sup>88</sup> See Rosenthal Report and Rosenthal Report Errata, at ¶ 76 and Table 3.

<sup>89</sup> Equal [REDACTED] less [REDACTED]. See Rosenthal Deposition Vol. 1, 81:8-81:15, 164:10-164:17, 200:19-201:11, 434:2-434:12.

<sup>90</sup> See Rosenthal Report and Rosenthal Report Errata, at ¶ 76 and Table 3.

<sup>91</sup> See Rosenthal Report, at ¶ 64.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

sales of prescription opioids over the time period 1993 to 2018.”<sup>92</sup> As evidence for her conclusion, she cites the fact that her preferred regression model has “an R-square of 0.9937, thus explaining over 99% of the variation in MME sales,” that her estimated “depreciation rate” is negative, and that the coefficient on her price index is negative and statistically significant.<sup>93</sup>

77. Professor Rosenthal’s direct model, however, does not reliably estimate the causal relationship between Defendants’ detailing and opioid prescriptions. Professor Rosenthal’s direct model can only be taken to demonstrate a correlation, not a true causal effect. In fact, Professor Rosenthal’s direct model suffers from a problem well known in the time series econometrics literature: the presence of “unit roots.” Put simply, a variable is said to have a “unit root” when its average value and its variance changes over time.<sup>94</sup> The presence of unit roots in time series data leads to the spurious regression problem.<sup>95</sup> A regression is said to be spurious when it shows a statistically significant relationship between variables when there is in fact no relationship.<sup>96</sup>
78. In her deposition, Professor Rosenthal testified that she conducted statistical tests for unit roots in her data and concluded that they were not present.<sup>97</sup> Professor Rosenthal is mistaken. I have conducted statistical tests for unit roots on the back up data underlying her direct model. The results of the tests strongly indicate the presence of unit roots in both her detailing stock and her opioid prescriptions variables.<sup>98</sup> Standard econometric techniques are

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<sup>92</sup> See Rosenthal Report, at ¶ 74.

<sup>93</sup> See Rosenthal Report, at ¶ 72.

<sup>94</sup> More precisely, a variable is said to have a unit root when a solution to its characteristic equation lies on the unit circle. See, e.g., Greene, William H. (1993). “Econometric Analysis.” 2<sup>nd</sup> ed. Macmillan, p. 564.

<sup>95</sup> See, e.g., Granger, C.W.J and P. Newbold. (1974). “Spurious Regressions in Econometrics.” *Journal of Econometrics*:2(2), at p. 117. See also Wooldridge, Jeffrey M. (2009). “Introductory Econometrics: A Modern Approach.” 4<sup>th</sup> ed. Cengage, Chapter 18.

<sup>96</sup> See Rubinfeld, Daniel. (2011). Reference Guide on Multiple Regression. 3<sup>rd</sup> ed. Federal Judicial Center, available at <https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf>, at p. 356.

<sup>97</sup> Specifically, Professor Rosenthal testified that she conducted the Dickey-Fuller test for unit roots; see Rosenthal Deposition Vol. 1, at p. 137:15-137:17 The Dickey-Fuller test is one of many diagnostic tests to examine whether a particular time series has unit roots. The null hypothesis for the Dickey-Fuller test is that the variable has a unit root. Thus, a p-value above standard significance levels (e.g. the 0.10 significance level) indicates that one cannot reject the null hypothesis of a unit root, and therefore regression analysis involving this time series may be susceptible to the spurious regression problem. See Wooldridge, Jeffrey M. (2009). “Introductory Econometrics: A Modern Approach.” 4<sup>th</sup> ed. Cengage, at pp. 630 – 635.

<sup>98</sup> I conduct the augmented version of Professor Rosenthal’s suggested Dickey-Fuller test, which adjusts for serial correlation in the error term. I also conduct the KPSS test for stationarity, which has a null hypothesis reversed

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

available to handle the existence of unit roots, but Professor Rosenthal does not employ them in her analysis.<sup>99</sup> Professor Rosenthal noted in her deposition that the presence of unit roots can lead regression results to be overstated:

Q. And would the presence of nonstationarity lead you to overstate the impact of promotion in your direct model?

A. Well, again, if the – if there was a unit root problem, then it could overstate the results, yes.<sup>100</sup>

79. Professor Rosenthal acknowledges issues with her chosen model yet nonetheless relies on it for her excess volume opinions.

**2. The estimated marketing depreciation rate lacks an adequate economic foundation and is only a convenient device to guarantee her assumed relationship between marketing and prescribing**

80. In Professor Rosenthal's direct model, the stock of promotion is estimated as detailing contacts in the current month plus the stock of prior detailing contacts. The stock of prior detailing contacts is a function of prior detailing contacts and a depreciation rate (shown in Equation 1 below). Professor Rosenthal does not specify a value for the depreciation rate of detailing contacts ( $\delta$  in Equation 1). Rather, the program selects a depreciation rate that produces the best fit for the data, given the model specifications for the estimation of total opioid MME volume (shown in Equation 2 below) (i.e. the stock of promotion,  $S_t$ , and total

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relative to the Dickey-Fuller test (*i.e.* the null hypothesis of the KPSS test is that the variable has no unit root and is stationary; in this sense, the KPSS test is more conservative than the Dickey-Fuller test). The results of these tests indicate that Professor Rosenthal's detailing stock and prescriptions variables contain unit roots. *See* Cantor supporting materials.

To illustrate the effect of the presence of unit roots in time series analysis, I have taken Professor Rosenthal's direct model and replaced her detailing contacts with data on US exports of sheep obtained from the United States Department of Agriculture Economic Research Service. Following her methodology, I allow for monthly sheep exports to enter "into the model as a stock, including the number of current sheep exports and the depreciated value of past sheep exports." Like Professor Rosenthal's model, the coefficients on sheep exports are statistically significant and positive, indicating a positive relationship between sheep exports and opioid prescriptions. The regressions also have R-square values in excess of 99%. *See* Cantor supporting materials for the results of this analysis.

<sup>99</sup> *See, e.g.,* Pindyck, Robert S. and Daniel L. Rubinfeld, *Econometric Models and Economic Forecasts*. 4<sup>th</sup> ed. Boston, MA: McGraw-Hill/Irwin, (1997); Section 16.4 discusses cointegration analysis, which can address the spurious regression issue under certain circumstances via error correction models. It is worth noting that the coefficients in a regression involving unit roots can still be directionally accurate, even if the magnitudes of the estimates may be incorrect.

<sup>100</sup> Rosenthal Deposition Vol. 1, at p. 139:19-139:24. *See also* Rosenthal Deposition Vol. 1, at p. 13816-138:20, "Q: And why is nonstationarity an issue with time series models? A: If you have this problem, which again, we do not, then you can get spurious results." In this context, "nonstationarity" refers to the presence of a unit root.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

opioid MME volume,  $Q_t$ , are simultaneously estimated). Therefore, similar to the turning points in marketing effectiveness described above, the stock of promotion is an estimated value, not an observable fact, and the specification of Equation 2 affects the selected depreciation rate.<sup>101</sup>

$$\text{Equation 1: } S_t = \text{Contacts}_t + (1 - \delta)S_{t-1}$$

$$\text{Equation 2: } Q_t = \alpha + S'_t\beta + X'_t\gamma + e_t$$

81. Professor Rosenthal references the work of Berndt, et al. in support of her methodology to calculate the stock of promotion.<sup>102</sup> Berndt, et al. present a methodology for estimating the stock of promotion for a single product market with the entry of competitors (in which products are used for a similar purpose and easily substitutable).<sup>103</sup> Professor Rosenthal improperly adapts Berndt, et al.'s methodology and applies it to an aggregated product class where products are not universally used for the same purpose (i.e. not perfect substitutes). For example, opioid products vary by MME (e.g., fentanyl versus morphine), by form (e.g., fentanyl patches versus oxycodone tablets), and indicated use (e.g., breakthrough cancer pain versus management of severe or chronic pain).<sup>104</sup> This is an inappropriate application of Berndt, et al.'s methodology.
82. Regarding her treatment of promotional stocks and flows, Exhibit 14 compares the flow of monthly detailing contacts (which only reaches a maximum of around [REDACTED] contacts) to Professor Rosenthal's estimation of promotional stock in Model B (which reaches a maximum of around [REDACTED] detailing contacts). Not only does Professor Rosenthal allow detailing contacts to *accumulate* with the stock of promotion (as shown by the green line in Exhibit 14 with a depreciation rate of 0.00), but Model B actually allows the stock to *appreciate* over time (as shown by the red line in Exhibit 14).

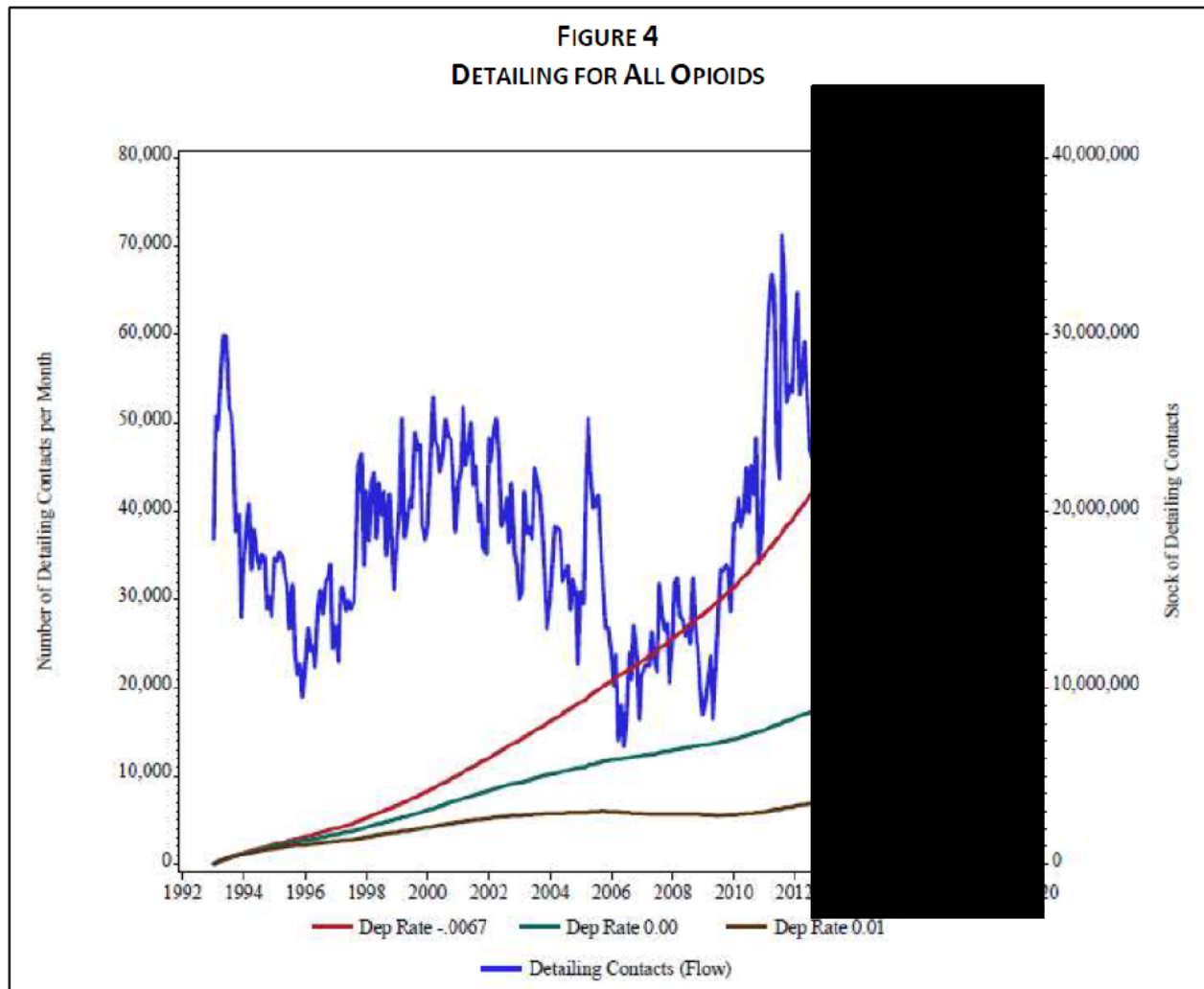
<sup>101</sup> See Rosenthal Report, at ¶¶ 61-62. Specifically, the program is selecting a depreciation rate that minimizes the sum of squared residuals for the estimation of total opioid MMEs.

<sup>102</sup> See Rosenthal Report, at ¶¶ 33 and 62.

<sup>103</sup> See E. Berndt, et al., "Information, Marketing and Pricing in the U.S. Antiulcer Drug Market," *American Economic Review*, 85(2), 1995, ("Berndt, et al."), at p. 101.

<sup>104</sup> See, e.g., Expert Report of Professor David Cutler, Data Appendix, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019) ("Data Appendix"), at pp. 13-14.

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**Exhibit 14: Contemporaneous Detailing Contacts per Month versus Stock of Detailing Contacts**

83. The effect of Professor Rosenthal's model specification on the estimated depreciation rate is exhibited by the variation across her three direct models. For Models A, B, and C, the monthly depreciation rate is equal to 0.05%, - 0.67%, and - 0.70%, respectively.<sup>105</sup> While Professor Rosenthal has a post-estimation rationale for Model B's negative depreciation rate of - 0.67%,<sup>106</sup> she does not provide any explanation as to the variation in her estimated

<sup>105</sup> See Rosenthal Report, at p. 47, Table 1.

<sup>106</sup> "The depreciation rate of -0.0067 translates to an annual rate of -8.3%. A negative depreciation rate indicates that the stock of promotion grows over time. While this prediction may be at odds with the usual marketing literature, it is perfectly consistent with an addictive product like opioids." See Rosenthal Report, at ¶ 72.

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depreciation rate or discussion of whether the variation affects her interpretation for Model B.<sup>107</sup>

84. An example helps to illustrate the implications of Professor Rosenthal's methodology. Using the depreciation rate in her preferred Model B, **one** contact performed in January 1993 translates to **4.08** marketing stock in July of 2010 (the height of opioid MMEs) and **7.65** marketing stock in May 2018 (the end of Professor Rosenthal's direct model analysis). This analysis produced implausible results, namely that one marketing contact performed 25 years ago resulted in **7,755** MMEs in May 2018.<sup>108</sup>
85. If the stock of promotion of detailing contacts is truly independent of the other explanatory variables, then the values of the depreciation rate should not be driven by the model specification. The fact that the depreciation rate is sensitive to the model specification undermines the reliability of depreciation as a legitimate construct.

**3. Professor Rosenthal's aggregate model produces inconsistent results for individual opioid molecules**

86. In her specification, Professor Rosenthal also assumes the relationship between detailing contacts related to opioid products and total opioid MME volume can be assessed for all opioid molecules at an aggregate level. Her report does not provide consideration for the relationship that may exist within each opioid molecule's market. In fact, marketing for two of the largest opioid molecules by MME (hydrocodone and oxycodone) peaked a decade (or more) before the height of opioid MME volume.
87. Exhibit 15 shows the difference between the Professor Rosenthal's aggregate measure of opioid detailing contacts and the specific molecule detailing contacts for hydrocodone and oxycodone, respectively.

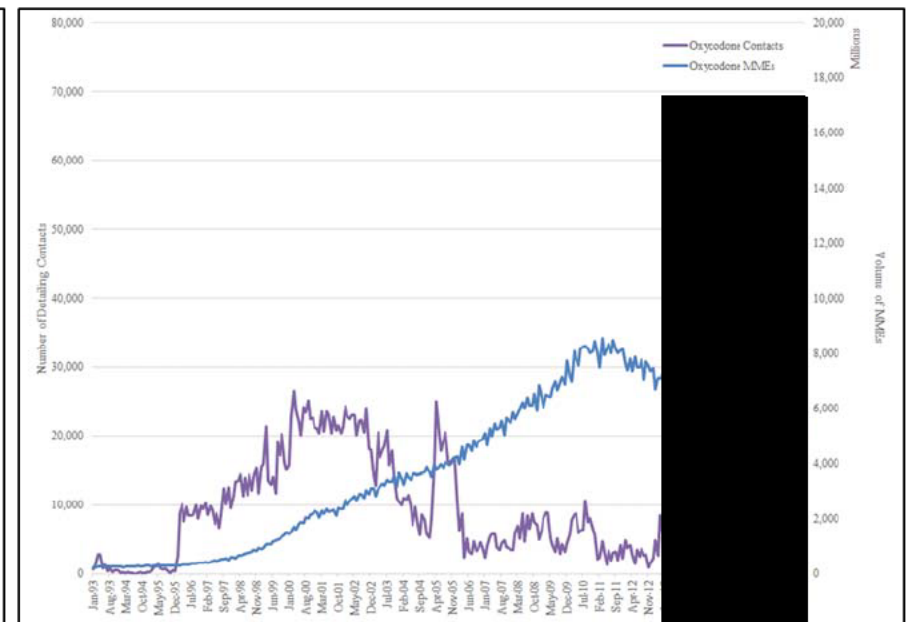
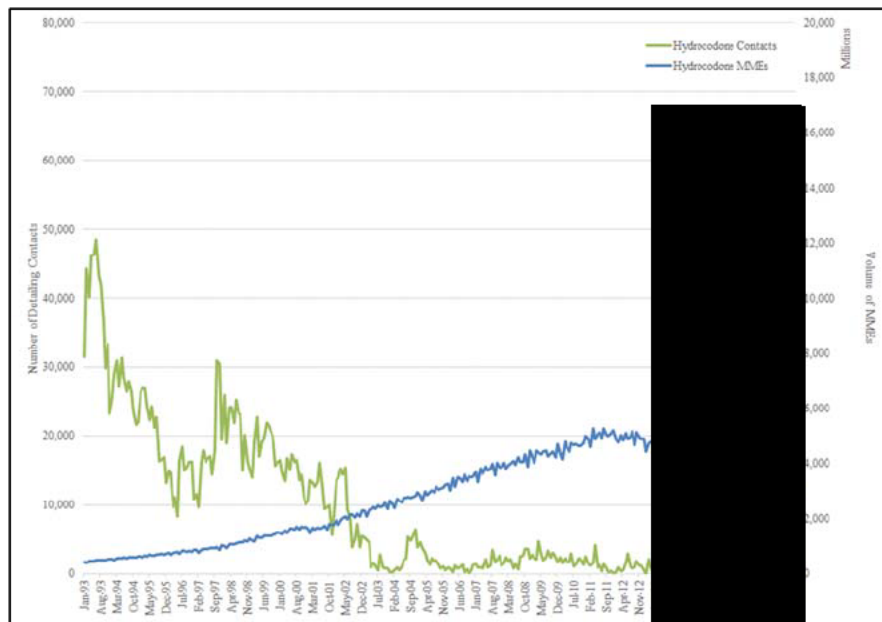
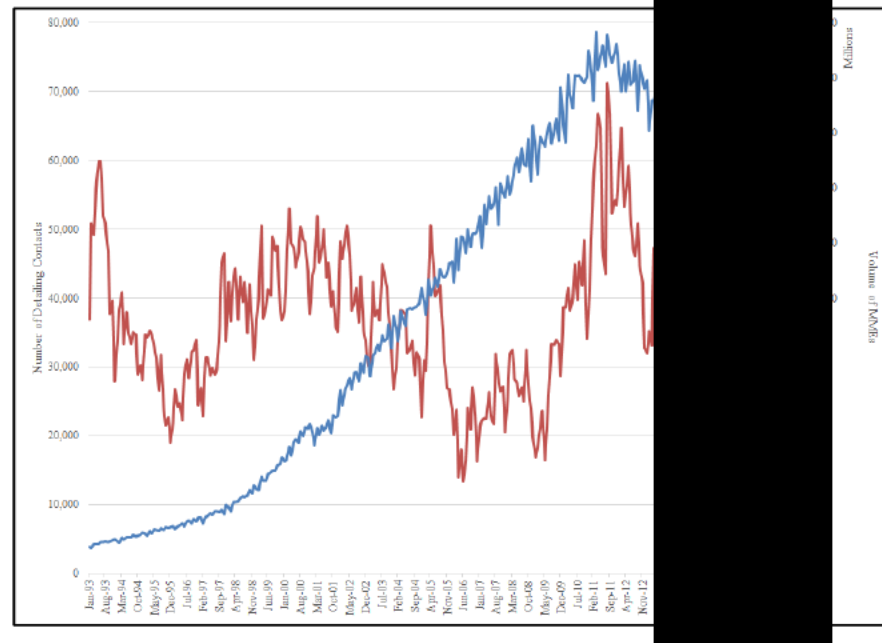
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<sup>107</sup> A paper by Berndt, et al. (cited by Professor Rosenthal) constrains estimated depreciation rates to values between 0 and 1, inclusive. See Berndt, Ernst R., et al., "The Roles of Marketing, Product Quality, and Price Competition in the Growth and Composition of the U.S. Antiulcer Drug Industry," *The Economics of New Good*, edited by Bresnahan, Timothy F. and Gordon, Robert J., 277-328 Chicago: University of Chicago Press, 1996, at p. 300.

<sup>108</sup> See Cantor supporting materials.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 15: Comparison of Opioid MMEs and Detailing Contacts for All Opioid Molecules vs. Specific Molecules**





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88. By assessing the relationship between detailing and opioid MME volume at an aggregate level, Professor Rosenthal is estimating a contrived relationship not reflecting any true market. This is demonstrated by the variation in model results and estimated depreciation rates when considering specific opioid molecules.
89. As described above, Professor Rosenthal's turning points in marketing effectiveness and decision to estimate the depreciation rate essentially guarantee her desired results. For example, marketing for hydrocodone peaked almost two decades before the height of opioid MME volume. Given that Professor Rosenthal has not provided an economic foundation for her turning points in marketing effectiveness and the volume of hydrocodone MME exhibits a similar trend to the overall market, I apply the same turning points in marketing effectiveness selected for Model B to a model for the hydrocodone market.
90. As shown in the model estimates below in Exhibit 16, the specification of Professor Rosenthal's model forces the flow of detailing contacts to fit the volume of opioid MMEs. The estimated depreciation rate varies for each molecule by both magnitude and sign. In the example of hydrocodone, the depreciation rate constant is negative (i.e. an appreciation of stock) and 1.4 times the size of the rate estimated for Model B. For the case of fentanyl, the depreciation rate constant is positive and .4 times the size of the rate estimated for Model B. Professor Rosenthal's post-estimation rationale for interpreting her estimated negative depreciation rate as consistent for addictive products is not sufficient to address the variation in depreciation rates when estimating by opioid molecule. Moreover, Professor Rosenthal further exacerbates the effects of this inconsistency. She does so by forcing the magnitude and pattern over time for the but-for detailing conditions to mimic the non-defendant information. The product results in the table below indicate that this treatment is unlikely to reflect the marketing patterns for Defendants in the absence of the Alleged Conduct.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 16: Professor Rosenthal's Preferred Model B by Opioid Molecule**

Parameter	Parameter Description	Rosenthal Model A	Rosenthal Model B	Hydrocodone	Fentanyl	Oxycodone	Morphine
$\alpha$	Constant						
$\beta$	Stock of Promotion						
$\beta_1$	Stock of Promotion * Regime Dummy until Mar2002						
$\beta_2$	Stock of Promotion * Dummy from Mar2002						
$\beta_3$	Stock of Promotion * Dummy Trend from Aug2010						
$\delta$	Depreciation Rate Constant						
$\gamma_6$	Aggregate Price Index						
R-Squared							
Adjusted R-Squared							

Sources: Rosenthal Report, supporting materials, IQVIA NPA, NSP, and IPS data.

91. Jointly, the issues above indicate that the results from Professor Rosenthal's direct model are driven by: (1) her use of three eras to fit the data; (2) failure to account for the time series properties of her data which make her model susceptible to the spurious regression problem; and (3) her use of a depreciation rate which necessarily forces a relationship between variables where none may exist.<sup>109</sup> As a result, Professor Rosenthal's direct model cannot measure the causal relationship between Defendants' contacts and opioid prescriptions reliably within a reasonable degree of professional certainty.

<sup>109</sup> There are myriad other econometric issues with Professor Rosenthal's direct model, including but not limited to: measurement error, endogeneity bias, and failure to adjust statistical significance for model specification search and multiple comparisons. In particular, Professor Rosenthal's assertion that "at that class level, industry level, these endogeneity questions do not pertain" is incorrect (Rosenthal Deposition Vol 2., at p. 500:8-500:10). Including the price of a good in a regression where the dependent variable is the quantity of that same good necessarily involves endogeneity bias. This is because both the supply curve equation and the demand curve equation both contain price and quantity. See Baker, Jonathan B., Daniel L. Rubinfeld. (1999). Empirical Methods in Antitrust Litigation: Review and Critique. *American Law and Economics Review*, 1(1/2), pp. 386 – 435, available at <https://cloudfront.escholarship.org/dist/prd/content/qt3mx7f6rd/qt3mx7f6rd.pdf>. Furthermore, the level of aggregation at which the regression analysis takes place does not affect the endogeneity bias. See, Rossi, P. (2013). Omitted Variables, Instruments and Fixed Effects. *Structural Econometrics Conference*, available at [https://faculty.fuqua.duke.edu/econometrics/presentations/2013/Rossi-Instruments and Fixed Effects.pdf](https://faculty.fuqua.duke.edu/econometrics/presentations/2013/Rossi-Instruments%20and%20Fixed%20Effects.pdf), at p. 26.

Generally speaking, these econometric issues cause estimated regression coefficients to be biased. Calculating the direction of this bias is not generally possible without strong assumptions on the nature of measurement error, the degree of endogeneity, and the specification search methodology. In a discussion about the relationship between price, demand, cost, and advertising for a hypothetical product, the Federal Judicial Center's *Reference Guide on Multiple Regression* states, "it is possible in some cases that both the outcome variable and the covariate each affect the other; if the expert does not take this more complex relationship into account, the regression coefficient on the variable of interest could be either too high or too low." See Rubinfeld, Daniel. (2011). *Reference Guide on Multiple Regression*. 3<sup>rd</sup> ed. Federal Judicial Center, p. 322, available at <https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf>. Professor Rosenthal's direct model assumes that Manufacturers do not change their level of detailing in response to changes in quantity.

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**C. Professor Rosenthal inadequately controls for increases in quantity demanded that can be explained by decreases in price**

**1. Professor Rosenthal does not consider that a decrease in the cost to the patient and payor drives an increase in quantity demanded**

92. Price plays a role in the equilibrium between supply and demand in most markets, including the opioid drug market, where, as prices decline quantity demanded increases.<sup>110</sup> In the prescription drug market, prices faced by uninsured consumers (i.e. where the individual is responsible for the full cost of the product) are higher than prices faced by insured consumers. In fact, prices related to consumers with prescription drug coverage through their insurer involve two components: (1) what the insurer pays to the pharmacy on behalf of the insured individual, referred to as “payer cost” or “payer price”, and (2) what the insured individual pays to the pharmacy, referred to as “out-of-pocket cost” or “out-of-pocket price”, in the form of copayment, coinsurance, or deductible.<sup>111</sup> A decline in either the payer price or the out-of-pocket price will cause downward movement along the demand curve. Likewise, an increase in the number of individuals with prescription drug insurance will cause downward movement along the demand curve because the out-of-pocket price to the insured consumer is less than the full cost of the drug. Exhibit 17 illustrates movement along the demand curve due to supply expansion (e.g., generic entry) and government subsidies (e.g., Medicare Part D and Social Security Disability Insurance).<sup>112</sup>

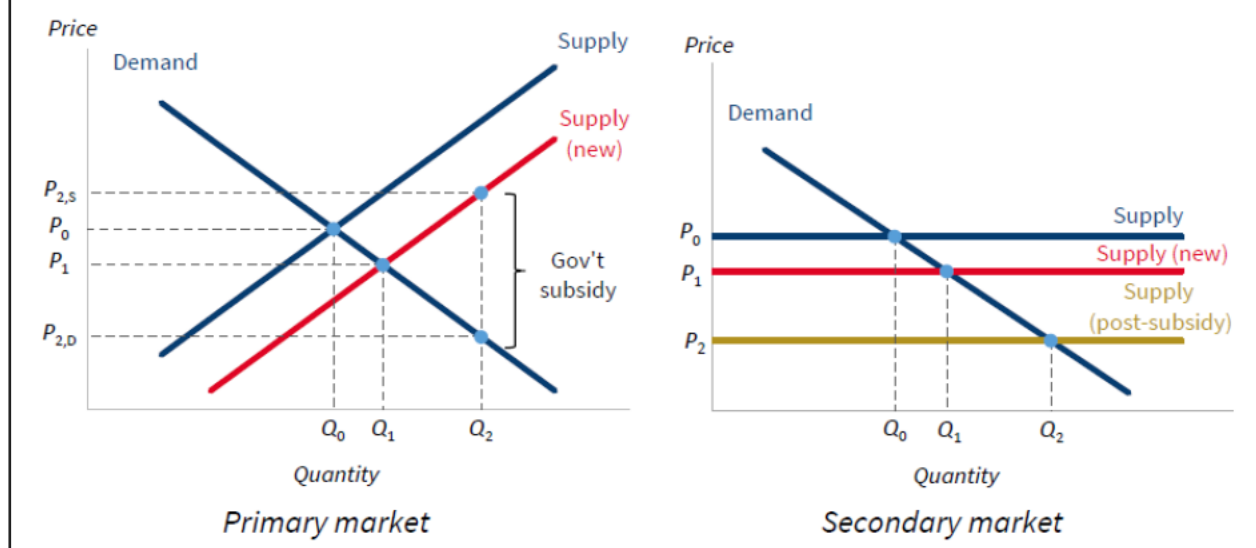
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<sup>110</sup> The supply and demand framework is discussed at length in The Role of Opioid Prices in the Evolving Opioid Crisis, The Council of Economic Advisers, April 2019. *See, e.g.*, The Council of Economic Advisers, “The Role of Opioid Prices in the Evolving Opioid Crisis,” (Apr. 2019) (“CEA Report”) at pp. 11-12; Grabowski, et al., “Updated Trends in US brand-name and generic drug competition,” *Journal of Medical Economics* (2016) 19:9, at pp. 836-844; Smith, D., “The Effects of Copayments and Generic Substitution on the Use and Costs of Prescription Drugs,” *Blue Cross and Blue Shield Association* (Summer 1993) 30, at pp.189-198; Danzon, P., “Price Discrimination for Pharmaceuticals: Welfare Effects in the US and the EU,” *International Journal of the Economics of Business* (1997) 4(3), at pp. 301-321.

<sup>111</sup> *See, e.g.*, Sood N., et al. “The Flow of Money Through the Pharmaceutical Distribution System,” Schaeffer Center for Health Policy & Economics, University of Southern California (Jun. 2017), available at [https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC\\_Flow-of-MoneyWhitePaper\\_Final\\_Spreads.pdf](https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC_Flow-of-MoneyWhitePaper_Final_Spreads.pdf).

<sup>112</sup> *See* CEA Report, at p. 2.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 17: Movement Along the Demand Curve due to Supply Expansions and Government Subsidies<sup>113</sup>****Figure 3. Effect of Supply Expansions and Government Subsidies on the Price and Quantity of Prescription Opioid Misuse**

93. Professor Rosenthal discusses prescription drug coverage and concludes that “insurance coverage is relatively comprehensive” and “the implication of generous insurance coverage is that consumers and their physician-agents will be relatively insensitive to the prices of prescription drug therapies.”<sup>114</sup> However, she fails to account for changes in prescription drug coverage over time or the impact that expanded insurance coverage in the U.S. had on opioid prices, demand for opioids, and opioid consumption. For example, in 2006 the Medicare program, which provides health insurance to American’s age 65 and older, for the first time provided coverage for prescription drugs.<sup>115</sup> Professor Rosenthal’s direct and indirect models do not accurately or adequately address the pricing dynamics in the opioid market or quantify the impact of price on demand.
94. The price index that Professor Rosenthal includes in her direct model is derived from IQVIA National Sales Perspective (NSP) data where the dollar value reflects pharmacy acquisition prices (i.e. what the pharmacy pays to a distributor or manufacturer before any discounts)

<sup>113</sup> See CEA Report, at p. 12, Figure 3.<sup>114</sup> See Rosenthal Report, at ¶ 16.<sup>115</sup> See CEA Report, at p. 16.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

and not actual prices to either the insurer or the consumer.<sup>116</sup> As such, Rosenthal's price index does not accurately capture (1) patient out-of-pocket price or (2) the payer price (i.e. the price the health insurer pays after manufacturer rebates and pharmacy reimbursements).<sup>117</sup> Professor Rosenthal's own statement regarding price sensitivity, acknowledges that health insurance coverage plays a causal role in demand for prescription drugs: "patients will tend to consume more prescription drugs than they would absent coverage."<sup>118</sup> However, her models do not incorporate a variable for prescription drug insurance coverage<sup>119</sup> and her price index does not properly reflect the price of opioids when accounting for insurance coverage. Exhibit 18 shows Professor Rosenthal's price index, which generally increases from 2001 through 2018.

95. The April 2019 White House Council of Economic Advisers (CEA) demonstrates both inaccuracies in Professor Rosenthal's price index discussed above. Because her price index relies on invoice prices to pharmacies, (1) she fails to capture off-invoice discounts to pharmacies and rebates to payers, both of which decrease the real supply price, and (2) she fails to capture patients' out-of-pocket prices, which decline as more individuals have drug coverage. Figure 6 from the CEA report, Exhibit 19, reflects a declining "Real Supply Price" from 2006 through 2014 and an even lower declining "Real Out-of-Pocket Price" to consumers.<sup>120</sup>

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<sup>116</sup> See, e.g., Appropriate Use of IMS Information, "Financial Community Presentation," (Nov. 12, 2009) *available at* [http://us.imshealth.com/marketing/fincom/appropriateuse\\_presentation.pdf](http://us.imshealth.com/marketing/fincom/appropriateuse_presentation.pdf), (accessed 5/2/2019), at p. 42. IQVIA Institute for Human Data Science, "Medicine Use and Spending in the U.S. A Review of 2017 and Outlook to 2022," (Apr. 2018), at pp. 43-44. Note, during the process of creating her price index, Professor Rosenthal limits the NSP data to the subset of products that also appear in the NPA data. During this process, Professor Rosenthal appears to have inadvertently excluded certain products from her price index calculation because her identification process did not properly capture the product's name, form, or strength (e.g., Duragesic). I have not attempted to correct Professor Rosenthal's product identification process. See Rosenthal Report, supporting materials.

<sup>117</sup> See, e.g., IQVIA Institute for Human Data Science, "Medicine Use and Spending in the U.S. A Review of 2017 and Outlook to 2022" (April 2018), at pp. 43-44.

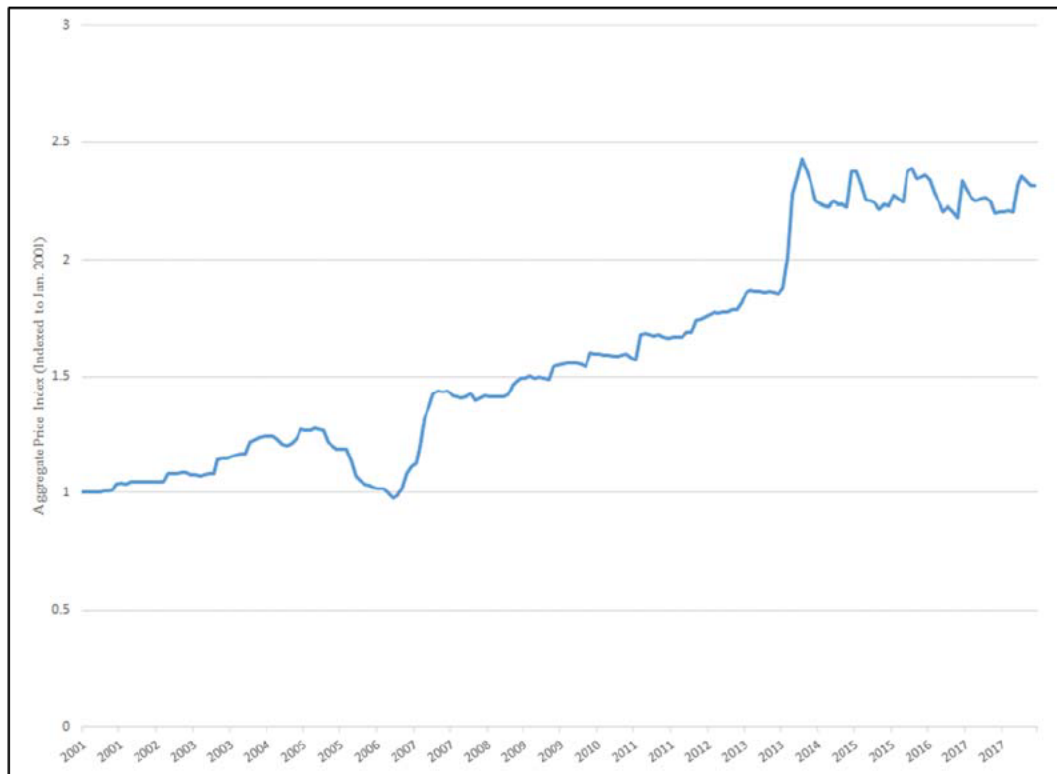
<sup>118</sup> See Rosenthal report, ¶17.

<sup>119</sup> Rosenthal's "Percent Uninsured" variable in her indirect model reflects the percent of individuals in each county that had no health insurance, this metric is not specific to prescription drug insurance coverage. As such, Rosenthal's model does not capture the significant volume of senior citizens who had no prescription drug insurance before the launch of Medicare Part D in 2006.

<sup>120</sup> See CEA Report, at p. 16, Figure 6.

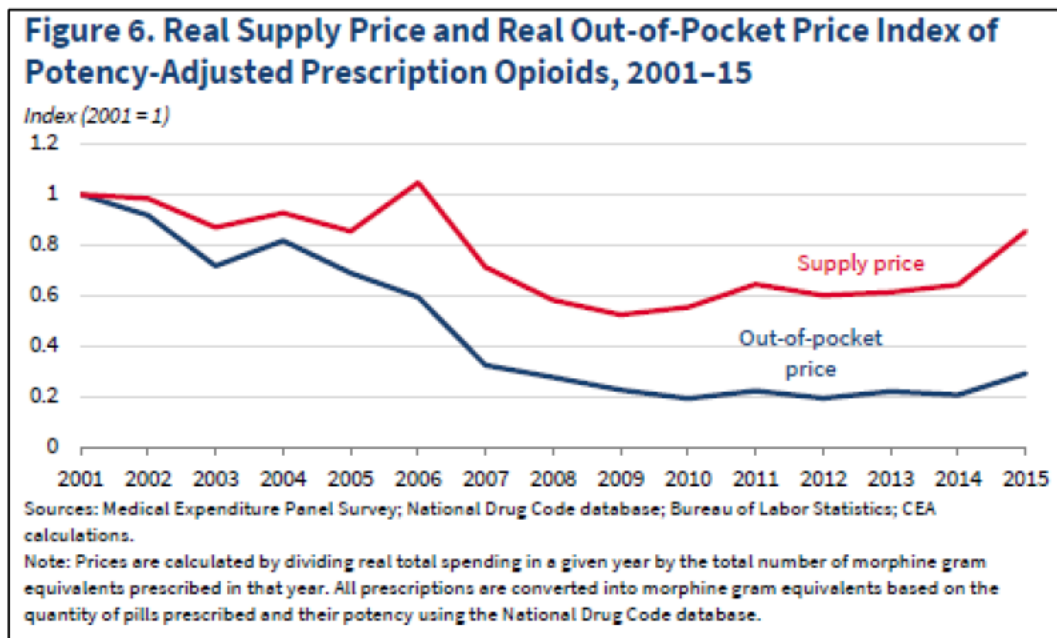
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**Exhibit 18: Professor Rosenthal's Monthly Aggregate Price Index (Re-indexed to Jan. 2001)**



**Source:** IQVIA NSP data; Rosenthal Report, supporting materials.

**Exhibit 19: Council of Economic Advisers Analysis of Prescription Opioid Prices<sup>121</sup>**





## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

96. The CEA study finds that “[b]etween 2001 and 2010, the out-of-pocket price of prescription opioids fell by 81 percent” and that “[t]he decline in out-of-pocket prices between 2001 and 2010 occurred in conjunction with a rising share of generic opioids in the market as well as increased public subsidies.”<sup>122</sup> The study notes that the share of cheaper generic opioids grew from 53% to 81% and the share of prescribed opioids purchased with public subsidies increased from 17% to 60% over the period. CEA went on to “estimate the contribution of an 81 percent price decline to the increase in sales” and found “that, without the price decline, per capita opioid sales would have increased, by half as much, or less, than the actual increase between 2001 and 2010.”<sup>123</sup> The analysis also “suggests that the observed decline in out-of-pocket prices for prescription opioids, which makes physician prescriptions more affordable for beneficiaries to fill, contributes to between 31 and 83 percent of the increase in overdose deaths involving prescription opioids between 2001 and 2010.”<sup>124</sup>
97. The net price to insurers influences the plan’s drug coverage decisions and member cost-sharing design, which in turn impact consumer demand. Pharmacy benefit managers (PBMs) and health plans direct members to lower cost drugs through the use of formularies (i.e. a list of drugs covered by the plan) and the plan’s member cost-sharing design (e.g., generics and lower cost brands are assigned lower member copays and/or coinsurance).<sup>125</sup>
98. Net prices to payers for brand drugs are reduced via rebates from the manufacturer.<sup>126</sup> Payers negotiate for rebates in exchange for encouraging use of the manufacturer’s drug through exclusion of competing drugs or preferential placement of the drug on formulary.<sup>127</sup> As net prices to PBMs and plans decrease, member cost-sharing also decreases and drug

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<sup>121</sup> See CEA Report, at p. 16, Figure 6.

<sup>122</sup> See CEA Report, at p. 5.

<sup>123</sup> See CEA Report, at pp. 5-7.

<sup>124</sup> See CEA Report, at pp. 5, 7.

<sup>125</sup> See, e.g., Berndt, Ernst R. 2002. “Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price.” *Journal of Economic Perspectives*. 16:4, at pp. 50-52. Huskamp, Haiden A. et al. 2003. “The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending.” *The New England Journal of Medicine*. December, 2003. 349:23. At p. 2225.

<sup>126</sup> See, e.g., Berndt, Ernst R. 2002. “Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price.” *Journal of Economic Perspectives*. 16:4, at p. 50.

<sup>127</sup> See, e.g. Hoadley, Jack, “Drug Pricing, Repricing, Rebates, and Patient Access”, *Health Policy Institute, Georgetown University*, (April 13, 2016), at pp. 24-25.



## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

consumption increases.<sup>128</sup> However, Professor Rosenthal does not account for the *real* price, which is decreasing and likely explains increased quantity demanded.

**2. Professor Rosenthal does not consider that lower generic prices drive an increase in quantity demanded**

99. Net drug prices to payers and consumers are also reduced through the availability of generics in the market. Once a brand drug's patent expires and generics enter the market competition among generic manufacturers drives down the price, as shown in Exhibit 17 above.<sup>129</sup> Many pharmacies negotiate discounts directly with generic manufacturers, which represent significant offsets to the invoice price Rosenthal captures in her models.<sup>130</sup> Insurers cover most generic drugs, particularly when there is more than one generic available, including State Medicaid plans, most of which require the use of generic drugs when possible.<sup>131</sup> Plans also typically place generics on formulary with the lowest member cost-sharing design in order to encourage members to use the lower priced generic product.<sup>132</sup> As noted in the CEA study discussed above, increased utilization of opioids was in part influenced by declines in member out-of-pocket prices which occurred in conjunction with a rising share of generic opioids in the market.<sup>133</sup> As such, Professor Rosenthal does not adequately account for the possibility the quantity of prescription opioids demanded by patients increase because treatment with opioids became more affordable.

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<sup>128</sup> See, e.g., Berndt, Ernst R. 2002. "Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price." *Journal of Economic Perspectives*. 16:4, at pp. 54.

<sup>129</sup> See, e.g., Berndt, Ernst R. 2002. "Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price." *Journal of Economic Perspectives*. 16:4, at pp. 59, 63. Kelton, Christina M. L. et al. 2007. "A General-Equilibrium Analysis of Public Policy for Pharmaceutical Prices." *Journal of Public Economic Theory*. 9:2, at p. 289.

<sup>130</sup> See, e.g. Hoadley, Jack, "Drug Pricing, Repricing, Rebates, and Patient Access", *Health Policy Institute, Georgetown University*, (April 13, 2016), at p. 11. Medicine Use and Spending in the U.S. A Review of 2017 and Outlook to 2022, April 2018, IQVIA Institute for Human Data Science, at pp. 43-44.

<sup>131</sup> See, e.g., Kelton, Christina M. L. et al. 2007. "A General-Equilibrium Analysis of Public Policy for Pharmaceutical Prices." *Journal of Public Economic Theory*. 9:2, at p. 297.

<sup>132</sup> See, e.g., Berndt, Ernst R. 2002. "Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price." *Journal of Economic Perspectives*. 16:4, at p. 50. Goldman, Dana P. et al. 2007. "Prescription drug cost sharing: associations with medication and medical utilization and spending and health." *The Journal of the American Medical Association*. July 2007. 04; 298(1), at p. 2.

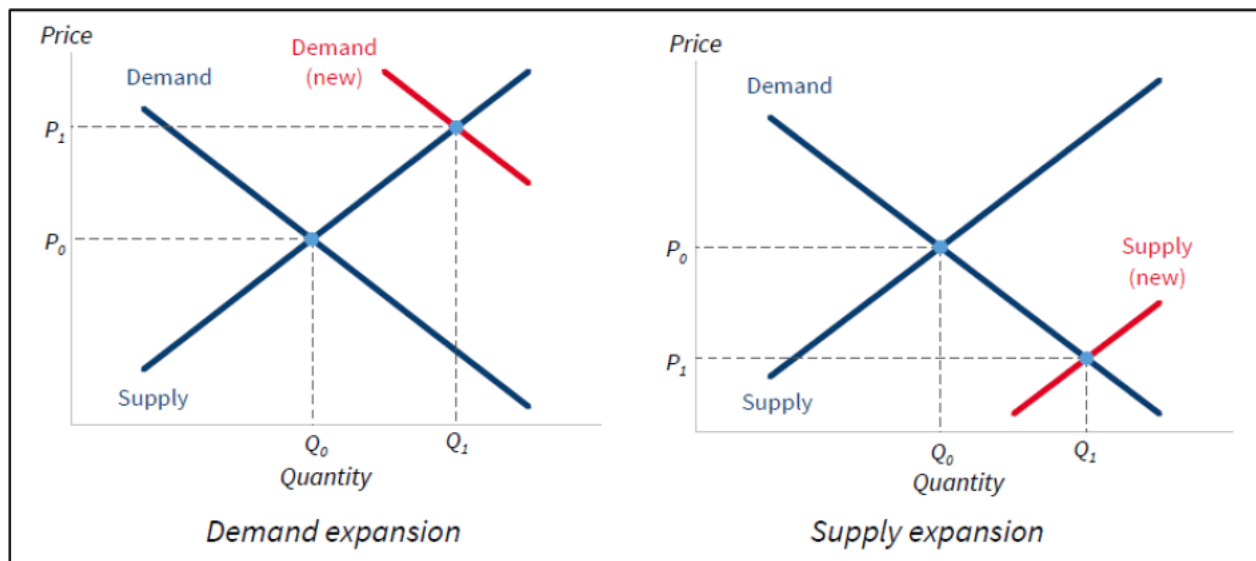
<sup>133</sup> See CEA Report, at p. 5.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**D. Professor Rosenthal inadequately controls for factors in the but-for world that would shift (or mitigate shifts) in quantity demanded and supplied**

100. Professor Rosenthal's direct model assumes that (1) the demand for undertreated pain was entirely created by manufacturers, (2) in the but-for world, marketing mimics the levels and patterns over time for non-defendant manufacturers, and (3) in the but-for world, other factors, not related to marketing or list price, would not affect the volume of prescription opioids. Professor Rosenthal's indirect model assumes that, in the but-for world, (1) the demand for prescription opioids is determined only by economic, demographic, and health factors (with only post estimation adjustments for price and secular growth) and (2) the relationship between these factors and prescription opioid volume does not change over time.<sup>134</sup> Professor Rosenthal cannot ignore important demand shifters in her definition of the but-for world. Exhibit 20 shows that the quantity of prescription opioids in the market is affected by the complex interaction of shifts in supply and demand, and Exhibit 21 lists several examples of supply and demand shifters, most of which Professor Rosenthal has not incorporated into her definition of the but-for world.

**Exhibit 20: Shifts in Demand and Supply<sup>135</sup>**



<sup>134</sup> See Rosenthal Report, at ¶ 79.

<sup>135</sup> See CEA Report, at p. 13, Figure 4.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 21: Table of Supply and Demand Shifters in the But-for World**

<b>Demand Shifter</b>	<b>Source(s)</b>
Economic, demographic, and health factors of patients	<i>See Rosenthal Report, ¶ 79</i>
State regulation (e.g., medical boards, PDMPs)	<i>See CEA Report, p. 10</i>
Cost of alternative treatments	<i>See Johns Hopkins 2018</i>
Access to health insurance coverage (e.g., Medicare Part D)	<i>See CEA Report, p. 18</i>
Cultural despair	<i>See Case and Deaton</i>
Medical guidelines and education	<i>See CEA Report, p. 7</i>
Patient medical conditions	<i>See Gruber Deposition, p. 441:22-442:11</i>
Prescriber preferences	<i>See Gruber Deposition, p. 441:22-442:11</i>
Pharmaceutical industry marketing	<i>See Gruber Deposition, p. 441:22-442:11</i>
Changing attitudes towards opioids	<i>See Gruber Deposition, p. 441:22-442:11</i>
Law enforcement environment, risk of using opioids illegally	<i>See Gruber Deposition, p. 441:22-442:11</i>

101. The CEA report discussed above quantified the impact of declining opioid prices on increased opioid use and misuse, driven primarily by expanded prescription drug coverage and generic opioid availability. However, the study noted that “falling out-of-pocket prices could not have led to a major rise in opioid misuse and deaths without the increased availability of prescription opioids resulting from changes in pain management practice guidelines that encouraged liberalized dispensing practices by doctors, illicit “pill mills,” increased marketing and promotion efforts from industry, and inadequate monitoring or control against diversion.”<sup>136</sup> Professor Rosenthal only addressed one of the causal factors mentioned by the CEA in her direct model, namely marketing by certain manufacturers. And her indirect model attributes all of the factors discussed by the CEA to “defendant misconduct” without analysis to support such an assumption.<sup>137</sup> The following represent just some of the factors that Professor Rosenthal failed to consider or account for in her analysis.

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<sup>136</sup> *See CEA Report, at p. 7.*

<sup>137</sup> *See Rosenthal Report, at ¶¶ 78-79.*

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**1. Professor Rosenthal does not consider Federal and State Rules that increased opioid consumption**

102. In the 1990s, patient pain advocacy groups and groups of pain specialists lobbied state Medical Boards and legislatures to change statutes and regulations to lift the relative prohibition on opioid use in the CNCP population.<sup>138</sup> At least 20 states liberalized use of opioids for CNCP based on “model” guidelines put forward by groups advocating for much more permissive use of opioids for CNCP.<sup>139</sup> Many states passed Intractable Pain Acts that removed sanctions for physicians who prescribed long-term opioid therapy.<sup>140</sup>
103. In 1998, a task force of the Federation of State Medical Boards released Model Guidelines for the Use of Controlled Substances for the Treatment of Pain, which were subsequently adopted as policy by the Federation’s House of Delegates.<sup>141</sup> These guidelines made three main policy statements:<sup>142</sup>
- a. “Controlled substances, including opioid analgesics, may be essential in the treatment of acute pain... and chronic pain.”
  - b. The legitimacy of the physician’s treatment of the patient would not be judged by “the quantity and chronicity of prescribing”.
  - c. Physicians may treat chemically dependent patients for pain with controlled substances.
104. The CEA report discussed above noted that one of the factors behind the decline in supply prices and out-of-pocket prices “was the inception of Medicare Part D in 2006, which introduced subsidies for prescription drugs, including opioid, and lowered the out-of-pocket price for enrolled consumers.”<sup>143</sup> Professor Rosenthal does not adequately control for these

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<sup>138</sup> See, e.g., Franklin, Gary M. "Opioids for chronic noncancer pain." *Neurology* 83.14 (2014), at p. 1277.

<sup>139</sup> See, Franklin, Gary M. "Opioids for chronic noncancer pain." *Neurology* 83.14 (2014), at p. 1277.

<sup>140</sup> See, e.g., Rummans, et al. “How Good Intentions Contributed to Bad Outcomes: The Opioid Crisis”, Mayo Clinic (March 2018), at pp. 345-346.

<sup>141</sup> See Johnson S. “Providing Relief to Those in Pain: A Retrospective on the Scholarship and Impact of the Mayday Project”, *The Journal of Law, Medicine, and Ethics*, Vol 31:1, (2013), at p. 16.

<sup>142</sup> See Johnson S. “Providing Relief to Those in Pain: A Retrospective on the Scholarship and Impact of the Mayday Project”, *The Journal of Law, Medicine, and Ethics*, Vol 31:1, (2013), at pp. 16-17. See also Federation of State Medical Boards, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain, Euless, Texas: Federation of State Medical Boards, (1998).

<sup>143</sup> See CEA Report, at p. 16.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

events. Further, analysis of Medicare drug coverage found that more than two-thirds of plans had no opioid prescribing restrictions from 2006 to 2011.<sup>144</sup> The existence of such policies (or lack thereof) are not accounted for in Professor Rosenthal's model.

**2. Professor Rosenthal does not consider that healthcare providers' attention to patient satisfaction increased opioid consumption**

105. In 2002, the Center for Medicare & Medicaid Services (CMS) and the Agency for Healthcare Research and Quality partnered to create the Hospital Consumer of Healthcare Providers and Systems (HCAHPS) Survey, which was intended to capture patients' perceptions of their hospital experience and to serve as a measure of healthcare quality.<sup>145</sup> The survey was first implemented in 2006<sup>146</sup> and contained three questions regarding pain control, intended to measure how well hospital providers manage patients with pain.<sup>147</sup>
106. The Deficit Reduction Act of 2005 further incentivized hospitals to participate in the HCAHPS Survey by imposing a 2% penalty on the hospital's Inpatient Prospective Payment System annual payment update in the case of non-submission of survey results.<sup>148</sup> In 2010, the Patient Protection and Affordable Care Act incorporated the HCAHPS Survey into its Hospital Value Based Purchasing program. The patient experience domain, measured by the HCAHPS Survey, comprised 30% of the total performance score in this calculation, therefore tying patients' perception of how their pain was managed to reimbursement under Medicare.<sup>149</sup> None of these developments are controlled for in Professor Rosenthal's model.

<sup>144</sup> See, e.g., Samuels, Elizabeth A. et al. 2017. "Observation: Brief Research Report. Medicare Formulary Coverage Restrictions for Prescription Opioids, 2006 to 2015." *Annals of Internal Medicine*, 167:12, (December 2017), at pp. 895-896.

<sup>145</sup> See Center for Medicare & Medicaid Services, "HCAHPS Fact Sheet," (Nov. 2017) *available at* [https://www.hcahpsonline.org/globalassets/hcahps/facts/hcahps\\_fact\\_sheet\\_november\\_2017.pdf](https://www.hcahpsonline.org/globalassets/hcahps/facts/hcahps_fact_sheet_november_2017.pdf), at p. 1.

<sup>146</sup> See Center for Medicare & Medicaid Services, "HCAHPS Fact Sheet," (Nov. 2017) *available at* [https://www.hcahpsonline.org/globalassets/hcahps/facts/hcahps\\_fact\\_sheet\\_november\\_2017.pdf](https://www.hcahpsonline.org/globalassets/hcahps/facts/hcahps_fact_sheet_november_2017.pdf), at p. 1, 3.

<sup>147</sup> See Rummans, et. Al. "How Good Intentions Contributed to Bad Outcomes: The Opioid Crisis", Mayo Clinic (March 2018), at pp. 346-347.

<sup>148</sup> See Center for Medicare & Medicaid Services, "HCAHPS: Patient Perspectives of Care Survey," *available at* <https://www.cms.gov/Medicare/Quality-Initiatives-patient-assessment-instruments/hospitalqualityinits/hospitalhcahps.html>

<sup>149</sup> See Rummans, et. Al. "How Good Intentions Contributed to Bad Outcomes: The Opioid Crisis," Mayo Clinic (March 2018), at p. 347.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**3. Professor Rosenthal does not consider that insurance coverage and higher cost of alternative treatments increased opioid consumption**

107. While numerous studies have shown that multidisciplinary pain management is the most clinically effective and cost-efficient means of treating most chronic pain conditions, many insurers do not cover multidisciplinary therapy but do cover opioid prescriptions.<sup>150</sup> These coverage decisions implicitly support chronic opioid therapy for chronic nonmalignant pain.<sup>151</sup> In September 2017, the New York Times published a story on the opioid crisis, concluding that “many insurers are limiting access to pain medications that carry a lower risk of addiction or dependence, even as they provide comparatively easy access to generic opioid medications. The reason, experts say: Opioid drugs are generally cheap while safer alternatives are often more expensive.”<sup>152</sup> Shortly thereafter, Senator Manchin of West Virginia sent a letter to two major health insurers asking that they remove barriers to non-opioid pain treatment.<sup>153</sup>
108. A 2018 study by the Johns Hopkins Bloomberg School of Public Health found that insurers may be inadvertently fueling the opioid epidemic by failing to apply evidence-based utilization management tools to discourage opioid overuse and encourage safer alternatives.<sup>154</sup> Senior study author G. Caleb Alexander states “Our findings suggest that both public and private insurers, at least unwittingly, have contributed importantly to the epidemic.”<sup>155</sup> The researchers found that a variety of elements of plan design may have contributed to opioid overuse. Until very recently, quantity limits used for opioids were typically set to 30, which has particular significance for opioids as the initial duration of early prescriptions “is associated with the likelihood that a patient will convert to chronic

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<sup>150</sup> See, e.g., Schatman M, “The Role of the Health Insurance Industry in Perpetuating Suboptimal Pain Management,” *Pain Management*, Vol 12:3, (2011) pp. 415-426.

<sup>151</sup> See, e.g., Schatman M, “The Role of the Health Insurance Industry in Perpetuating Suboptimal Pain Management,” *Pain Management*, Vol 12:3, (2011) pp. 415-426.

<sup>152</sup> See Thomas, Katie and Ornstein, Charles, “Amid Opioid Crisis, Insurers Restrict Pricey, Less Addictive Painkillers,” *The New York Times* (Sep. 17, 2017) available at <https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html>.

<sup>153</sup> See, e.g., Ornstein, Charles, “Senator Calls on Insurers to Improve Access to Non-Opioid Pain Treatments,” *Pro Publica* (Sep. 27, 2017)

<sup>154</sup> See “Health Insurance Plans May Be Fueling Opioid Epidemic”, Johns Hopkins School of Public Health press release (Jun. 22, 2018) available at <https://www.jhsph.edu/news/news-releases/2018/health-insurance-plans-may-be-fueling-opioid-epidemic.html> (“Johns Hopkins 2018”).

<sup>155</sup> See Johns Hopkins 2018.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

use.”<sup>156</sup> Further, the researchers found few step therapy requirements in place for opioids and that prior authorization requirements were in place for only a minority of opioids. Researchers also found that insurers tended to make opioids available relatively cheaply to patients, placing 74% of opioids on Tier 1.<sup>157</sup> Despite the data just discussed, Professor Rosenthal did not account for the possibility that opioid prescriptions were driven by insurance coverage determinations.

**4. Professor Rosenthal does not consider that physician attitudes towards treatment of pain increased opioid consumption**

109. Physicians’ attitude towards the treatment of pain with prescription opioids impacts the demand for opioid products. I understand from Counsel that Defendants’ expert, Dr. Weinberger, will opine on the history of physician attitudes around pain management. Professor Rosenthal has attempted to account for changing attitudes towards pain treatment through the direct model’s three eras of marketing effectiveness. In doing so, she attributes the changing attitudes during the 1990s and early 2000s to Defendant manufacturers’ Alleged Conduct. Defendant manufacturers’ liability on regarding this factor is disputed, and Professor Rosenthal’s preferred direct model cannot distinguish different influences on marketing effectiveness to address alternative liability assumptions about physician attitudes.

**5. Professor Rosenthal does not consider that cultural despair increased opioid consumption**

110. Professors Anne Case and Angus Deaton observe that mortality rates for less educated non-Hispanic whites in the U.S. has increased since the turn of the century, mainly driven by rises in deaths of despair, i.e. deaths caused by suicide, drug overdose, and alcohol.<sup>158</sup> While a largely-accepted economic answer is that the fall in real wages explains the rise in mortality, Case and Deaton argue that declines in the labor force and decays in traditional

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<sup>156</sup> See Johns Hopkins 2018.

<sup>157</sup> See Johns Hopkins 2018.

<sup>158</sup> See Case, Anne and Angus Deaton, “Mortality and Morbidity in the 21st Century,” *Brookings Papers on Economic Activity* (Spring 2017), 397-476 (“Case and Deaton”), at p. 398.



## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

social structures formed a cumulative disadvantage for this demographic class, resulting in higher incidences of suicide, drug overdose, and alcohol-related deaths.<sup>159</sup>

111. By 2015, mortality rates from deaths of despair had doubled since 1990, to 80 deaths per 100,000.<sup>160</sup> The epidemic began in the Southwest in 2000, spread to the Southeast and the West Coast by the mid-2000s, and is now a countrywide phenomenon; furthermore, there is no discernible difference between rural and urban areas.<sup>161</sup> While mortality from deaths of despair and all-cause mortality are highly correlated, the authors observe that “deaths of despair are a large and growing component of midlife all-cause mortality.”<sup>162</sup> The authors largely dismiss the fall in real wage as a major factor in the higher mortality rate – “the changes in mortality and morbidity are only coincidentally correlated with changes in income.”<sup>163</sup>
112. Case and Deaton believe that systematic changes, beginning in the early 1970s which made life more difficult for those without a college degree, resulted in higher rates of suicides, drug overdoses, and alcohol-related deaths. Traditional structures weakened – unions diminished, marriage rates fell, religious practices began to emphasize the importance of “seeking an identity.”<sup>164</sup> People in this cohort were faced with fewer social systems of support than their predecessors, resulting in the self-perception of failure. In short, there was a “loss of the structures that give life a meaning.”<sup>165</sup> Apart from the decay in social institutions, labor force participation among men fell – after the birth cohort of 1940, men with less than a college education were less likely to be employed or look for work at any given age.<sup>166</sup> This effect formed a vicious feedback loop, i.e. with fewer men working, fewer marriages occurred, rates of cohabitation rose, and the number of children born out of wedlock increased, which further denigrated family stability, a factor considered vital for social health.<sup>167</sup> The authors believe that a case can be made that a loss in America’s defining

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<sup>159</sup> See Case and Deaton, at pp. 397 – 398.

<sup>160</sup> See Case and Deaton, at p. 408.

<sup>161</sup> See Case and Deaton, at p. 409.

<sup>162</sup> See Case and Deaton, at p. 414.

<sup>163</sup> See Case and Deaton, at p. 420.

<sup>164</sup> See Case and Deaton, at pp. 429-430.

<sup>165</sup> See Case and Deaton, at p. 430.

<sup>166</sup> See Case and Deaton, at pp. 431-432.

<sup>167</sup> See Case and Deaton, at pp. 431-432.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

virtue – industriousness, resulting from lower labor force participation rates – can explain the rise in deaths of despair.<sup>168</sup>

113. The authors thus describe two interrelated factors that explain why more individuals, specifically whites without a college degree, have turned to drugs and alcohol as a respite from the increased social instability: the changing labor market, caused by globalization and technical change, and the loss in virtue, with the former acting as the fundamental force.<sup>169</sup> “Increasing distress, and the failure of life to turn out as expected, are consistent with people compensating through other risky behaviors such as abuse of alcohol and drug use that predispose towards the outcomes we have been discussing.”<sup>170</sup>
114. Professor Rosenthal disregards cultural despair’s documented causal influence on the total volume of opioid MMEs in the market. Professor Cutler agrees that despair leads to opioid consumption, stating that “[t]emporary despair can lead people to take pain relievers.”<sup>171</sup> Therefore, Professor Cutler points out a factor in opioid consumption that Professor Rosenthal has failed to consider and incorporate into her analysis.

**E. Professor Rosenthal does not provide an analysis of the relationship between alleged diversion and increased opioid volume**

115. Professor Rosenthal does not separately examine the causality of diversion by third parties, which clearly depends on other participants in the supply chain, including conduct of dispensers (so called “pill mills”), and behavior of corrupt doctors and patients. She does not present a direct analysis of the effect of diversion on total opioid MME volume in the market.<sup>172</sup> Her direct model is unable to capture changes in incentives for non-manufacturers to engage in illicit behavior to divert product. In addition, she explains that her indirect (residual) model is intended to capture other sources of marketing Alleged Conduct, not diversion.<sup>173</sup> Diversion is a considerable factor in Plaintiffs’ damages claims and Professor Rosenthal does not discuss, address, or provide a direct analysis of the Defendants’ diversion

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<sup>168</sup> See Case and Deaton, at p. 433.

<sup>169</sup> See Case and Deaton, at p. 433.

<sup>170</sup> See Case and Deaton, at p. 434.

<sup>171</sup> See Case and Deaton, at p. 451.

<sup>172</sup> See Rosenthal Report, at ¶¶ 7 and 78; Rosenthal Deposition, 33:21-34:2.

<sup>173</sup> See Rosenthal Report, at ¶ 78.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

Alleged Conduct and its causal relationship to prescriptions or shipments. Therefore, Professor Rosenthal's analyses are inadequate to address diversion causality.

**F. Professor Rosenthal does not adequately consider uncertainty in her indirect approach**

**1. The indirect model assumes the relationship established in the 1997 baseline holds for every year after, leading to uncertainty in the model results for 1998-2016**

116. Professor Rosenthal's indirect approach cannot account for variation over time that is not captured by explanatory variables in the 1997 baseline estimation. The relationship between opioid shipments per capita and the demographic, economic, and health factors established in the 1997 baseline are held constant for Professor Rosenthal's predictions in every year after, and any difference between actual and predicted shipments is deemed due to Defendants' Alleged Conduct. The only temporal adjustment applied to the indirect model results are (1) a secular trend and (2) a price adjustment.<sup>174</sup> Therefore, Professor Rosenthal is effectively assuming that the lawful drivers of opioid shipments are unchanged over time (outside of price and a secular trend). If there is any evidence that this is untrue, then generating future predicted values based on the relationship estimated in 1997 is flawed.
117. Professor Rosenthal does not acknowledge the uncertainty of her predictions using the indirect approach. However, when applying an indirect approach in his analysis, Professor Cutler does acknowledge this uncertainty, "The indirect regression attributes the entirety of unexplained opioid-related mortality to shipments. To the extent that other factors not modelled in the 'baseline' regression contributed to increases in opioid mortality, the indirect approach has the potential to overstate the impact of defendants' actions."<sup>175</sup> This statement is equally applicable to Professor Rosenthal's but-for predictions of shipments.

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<sup>174</sup> See Rosenthal Report, at ¶¶ 87-88. In my analysis of Professor Rosenthal's indirect model, I implement, but do not accept, her price adjustment using the price index coefficient from her direct model. As discussed above, there are several issues with Professor Rosenthal's price index that can also impact the reliability of her indirect model results due to her use of this coefficient. Additionally, in my analysis, I implement, but do not accept, her use of the secular trend.

<sup>175</sup> See Cutler Report, at fn 53.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

118. Professor Rosenthal’s indirect approach prediction methodology relies on the assumption that there are no patterns in her residuals, or that they are pure noise.<sup>176</sup> She has not demonstrated that her residuals are uncorrelated with measurable factors such as county geography.
119. In addition to potentially overstating shipments due to Defendant Alleged Conduct, Professor Rosenthal’s indirect approach cannot apportion excess shipments among defendants or differentiate between defendant and non-defendant actions.

**2. The indirect model shows excess shipments for the “pre-misconduct” baseline, which indicates predicted excess shipments may be over estimated**

120. Professor Rosenthal’s indirect approach relies entirely on the assumption that demographic, economic, and health care characteristics can describe opioid shipments in a period without Defendants’ Alleged Conduct. If this assumption does not hold because other factors, not related to Defendants’ Alleged Conduct, affect opioid shipments, then attributing the model’s residual to Defendants’ Alleged Conduct is an overestimation.
121. Given Professor Rosenthal’s indirect approach framework, the residual in the baseline should be equal to zero because 1997 is defined as a “pre-misconduct” period.<sup>177</sup> However, Professor Rosenthal’s indirect model has a residual equal to 15.2% in the 1997 baseline.<sup>178</sup>

**3. The indirect model relies on a baseline year of interpolated explanatory variables, which introduces uncertainty to the results**

122. The Data Appendix, referenced in Professor Cutler’s report, describes the creation of a dataset containing county-level demographic and economic variables.<sup>179</sup> I understand that this Data Appendix reflects the creation of materials shared by Professor Rosenthal, Professor Cutler, and Professor Jonathan Gruber and used specifically in Professor Rosenthal’s indirect approach. As shown in Exhibit 22, the Data Appendix indicates linear

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<sup>176</sup> See, e.g., Wooldridge, Jeffrey M. (2009). “Introductory Econometrics: A Modern Approach.” 4<sup>th</sup> ed. Cengage, p. 208.

<sup>177</sup> See Rosenthal Report, at ¶ 79.

<sup>178</sup> See Rosenthal Report, at p. 61, Table 5.

<sup>179</sup> See Data Appendix, at pp. 22-25.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

interpolation was used to bridge gaps across years with missing information. There are two time periods with missing information for education, employment, income, poverty, and urban variables: 1991-1999 and 2001-2006 (urban statistics are also missing information through 2010). Additionally, for missing information at the end of the time series, values are held constant for urban and industry variables.<sup>180</sup>

**Exhibit 22: Data Appendix, Exhibit 2 – Economic and Demographic Variables with Data Sources and Years Reported<sup>181</sup>**

Table 2 Economic and Demographic Variables with Data Sources and Years Reported																												
Year	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
<b>Population Characteristics</b>																												
- Population																												
- Percent Male/Female	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
- Percent <15, 15-29, 30-44, 45-64, 65+	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP	PEP
- Percent White/Black/Other																												
- Percent Hispanic																												
<b>Education</b>																												
- Percent Less than High School	1990										2000							2005-2006-2007-2008-2009-2010-2011-2012-2013-2014-2015-2016-2017										
- Percent High School Only	Census										Census							ACS										
- Percent Some College																												
- Percent College or Higher																												
<b>Employment Statistics</b>																												
- Employment to Population Ratio	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
- Unemployment Rate	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS	BLS
<b>Median Household Income</b> (Converted to 2010 Dollars using Annual CPI data)																												
	1990										2000							2005-2006-2007-2008-2009-2010-2011-2012-2013-2014-2015-2016-2017										
	Census										Census							ACS										
																		ACS										
<b>Poverty Rate</b>																												
	1990										2000							2005-2006-2007-2008-2009-2010-2011-2012-2013-2014-2015-2016-2017										
	Census										Census							ACS										
																		ACS										
<b>Percent Urban</b>																												
	1990										2000																	
	Census										Census																	
<b>Industry Characteristics</b>																												
- Percent Agriculture/Mining/Construction/Utilities																												
- Percent Manufacturing	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
- Percent Retail/Transportation	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP	CBP
- Percent Professional Services																												
- Percent Health Care/Accommodation/food/Other Services																												
<b>Notes:</b> PEP: US Census Bureau Population Estimates Program ACS: 5-year American Community Survey Census: Decennial Census BLS: Bureau of Labor Statistics Local Area Unemployment Statistics program. CBP: County Business Patterns When necessary, rates are calculated using relevant population from the Population Estimates Program. Interpolated values are a linear interpolation between the preceding and following measured value.																												

Notes: PEP: US Census Bureau Population Estimates Program  
 ACS: 5-year American Community Survey  
 Census: Decennial Census  
 BLS: Bureau of Labor Statistics Local Area Unemployment Statistics program.  
 CBP: County Business Patterns  
 When necessary, rates are calculated using relevant population from the Population Estimates Program.  
 Interpolated values are a linear interpolation between the preceding and following measured value.

123. As shown in Exhibit 22, Professor Rosenthal's 1997 baseline cross-sectional model is estimated using interpolated values for education, income, poverty, and urban explanatory variables. By using interpolated explanatory variables to estimate the baseline relationship, she introduces unnecessary uncertainty into her model estimations and subsequent predictions. To avoid the uncertainty due to interpolated values, Professor Rosenthal could have used 2000 as the baseline year for the indirect approach. 2000 is only three years after her current baseline and actual values (not interpolated values) are available for all

<sup>180</sup> See Data Appendix, at pp. 22-25.

<sup>181</sup> See Data Appendix, at Table 2, p. 25.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

explanatory variables. Exhibit 23 displays the indirect model estimates of excess MMEs (50.4%) when using 2000 as the baseline year, instead of 1997.

**Exhibit 23: Indirect Method Excess Shipments in MMEs (Baseline Year of 2000)**

Year	Actual MME (MM)	Excess Shares	
		1997 [1]	2000 [2]
1997	24,453		
1998	29,531	21.9%	
1999	35,184	30.2%	
2000	45,632	43.5%	
2001	54,996	51.2%	17.9%
2002	64,797	56.8%	26.3%
2003	78,588	63.2%	36.8%
2004	87,184	65.8%	41.2%
2005	91,151	65.8%	41.6%
2006	105,632	69.0%	47.5%
2007	122,327	72.4%	53.3%
2008	128,995	73.1%	54.4%
2009	139,151	74.5%	55.7%
2010	153,408	75.8%	58.2%
2011	154,723	75.4%	58.0%
2012	150,084	74.2%	56.8%
2013			
2014			
2015			
2016			
<b>Total</b>			

**Notes:**

[1] The excess share using Rosenthal's indirect model with 1997 as the baseline year.

[2] The excess share using Rosenthal's indirect model with 2007 as the baseline year.

**Sources:** Rosenthal Report, Table 5 and supporting materials.

124. Due to the role of interpolation in Professor Rosenthal's approach, it is entirely possible that there are substantial discrepancies occurring between the interpolated baseline values and the true measures. This introduces uncertainty to Professor Rosenthal's indirect approach conclusions, which are expanded upon by Professor Cutler's use of her results.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**4. The indirect model is an improper framework because it cannot accurately account for changes in the market over time**

125. As discussed above, Professor Rosenthal's indirect approach cannot account for variation over time that is not captured by explanatory variables in the 1997 baseline estimation, and the only temporal adjustment applied to the indirect model results are (1) a secular trend and (2) a price adjustment.<sup>182</sup> For example, changes in prescription drug insurance coverage over time (e.g., implementation of Medicare Part D in 2006) cannot be appropriately captured through the indirect approach. Also as discussed above, Professor Rosenthal's price index is not reflective of real supply prices or patient out-of-pocket prices in the market place, and therefore the impact of declining prices has not been accounted for in her indirect model.
126. Exhibit 24 displays the indirect model estimates of excess MMEs (6.5%) when using 2007 as the baseline year, instead of 1997. 2007 is after the implementation of Medicare Part D and does not have any interpolated values, except for percent urban. This example demonstrates Professor Rosenthal's indirect model's substantial sensitivity to a change in the baseline year and further indicates the considerable uncertainty in her estimates of excess MMEs.

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<sup>182</sup> See Rosenthal Report, at ¶¶ 87-88.



## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 24: Indirect Method Excess Shipments in MMEs (Baseline Year of 2007)**

Year	Actual MME (MM)	Excess Shares	
		1997 [1]	2007 [2]
1997	24,453		
1998	29,531	21.9%	
1999	35,184	30.2%	
2000	45,632	43.5%	
2001	54,996	51.2%	
2002	64,797	56.8%	
2003	78,588	63.2%	
2004	87,184	65.8%	
2005	91,151	65.8%	
2006	105,632	69.0%	
2007	122,327	72.4%	
2008	128,995	73.1%	3.0%
2009	139,151	74.5%	1.4%
2010	153,408	75.8%	6.6%
2011	154,723	75.4%	7.7%
2012	150,084	74.2%	7.5%
2013			
2014			
2015			
2016			
<b>Total</b>			

**Notes:**

[1] The excess share using Rosenthal's indirect model with 1997 as the baseline year.

[2] The excess share using Rosenthal's indirect model with 2007 as the baseline year.

**Sources:** Rosenthal Report, Table 5 and supporting materials.

**5. Professor Rosenthal cannot be certain that her predictions are different from the actual world, and this uncertainty compounds over time**

127. As noted previously, Professor Rosenthal's indirect regression model is a forecasting model wherein she estimates the association between opioid shipments and various demographic factors in 1997 and uses those estimated relationships to predict opioid shipments for

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

counties through 2016.<sup>183</sup> Professor Rosenthal's Table 5 shows the point estimates from her forecasts, but fails to show the uncertainty inherent in those point estimates. There are two sources of uncertainty in her forecasts: 1) the uncertainty of the estimated relationships in the baseline period, and 2) the inherent variation in opioid shipments across counties in her sample.<sup>184</sup> During their depositions, both Professors Rosenthal and Cutler recognized the uncertainty of out-of-period predictions:

**Professor Rosenthal:** “[I]t's generally good practice in applied economic analysis to not extrapolate too far outside of the world you're analyzing. So we don't want to forecast 50 years out from this model.”<sup>185</sup>

**Professor Cutler:** “[Y]our model can give you an estimate, but that is so far out of the range of the data that you observe that you wouldn't trust that model even though it can give you an estimate[.]”<sup>186</sup>

128. There are standard formulae to quantify the uncertainty for predicted values from a regression model; I apply those formulae to quantify the uncertainty in her forecasts and show the results in Exhibit 25, below.

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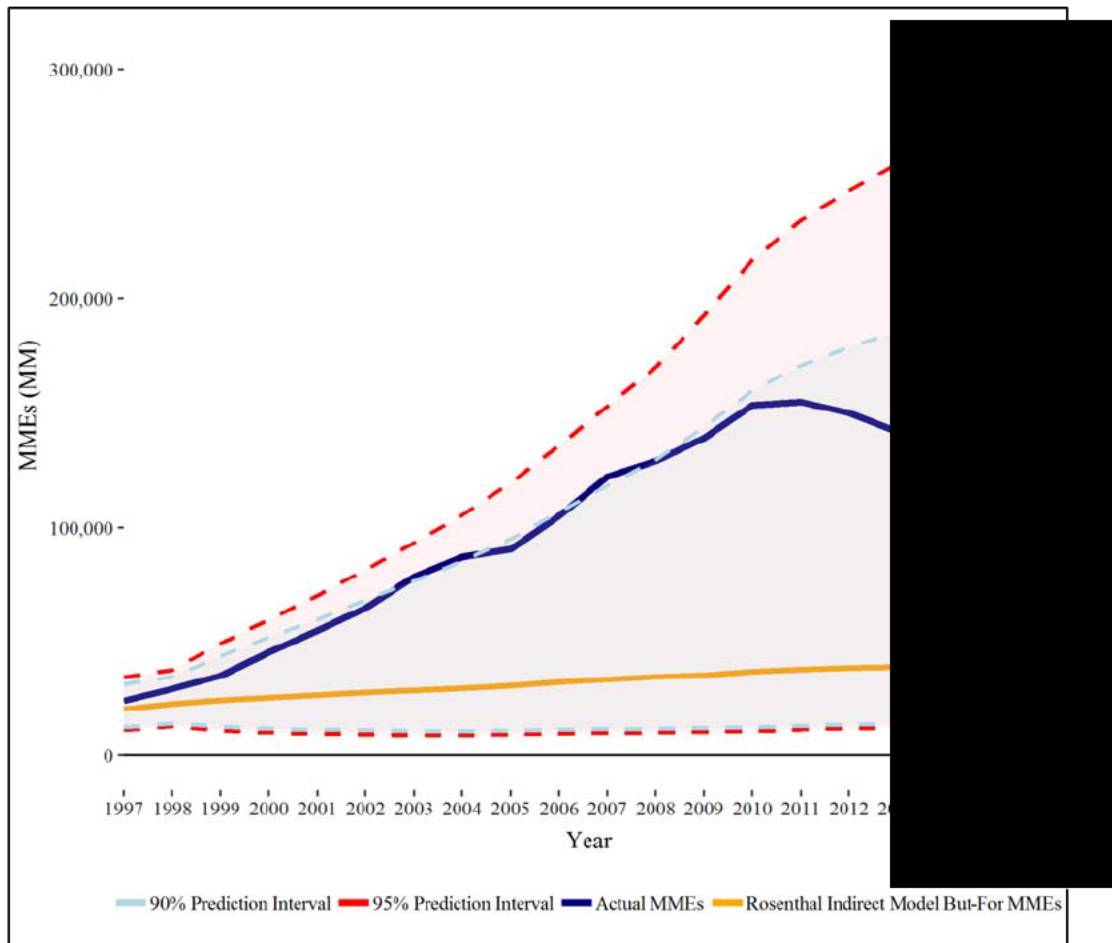
<sup>183</sup> The dependent variable in Professor Rosenthal's indirect regression model is the natural log of opioid shipments per capita per day, as measured from the ARCOS Large County sales data. *See* Rosenthal Table 4, ¶¶ 87-88. As discussed previously, Professor Rosenthal makes *post hoc* adjustments to the predictions from her regression model to account for trends in opioid shipments and changes in price that are not explicitly accounted for in her regression. These adjustments are reflected in Exhibit 25, below.

<sup>184</sup> *See, e.g.,* Wooldridge, Jeffrey M. (2009). “Introductory Econometrics: A Modern Approach.” 4<sup>th</sup> ed. Cengage, pp. 206 – 215. Note that confidence intervals at a particular value of the explanatory variables in a regression model are different from prediction intervals. Professor Wooldridge explains, “a confidence interval for the average person in the subpopulation is not the same as a confidence interval for a particular unit (individual, family, firm, and so on) from the population. In forming a confidence interval for an unknown outcome on [the dependent variable], we must account for another very important source of variation: the variance in the observed error, which measures our ignorance of the unobserved factors that affect [the dependent variable].” Wooldridge, Jeffrey M. (2009). “Introductory Econometrics: A Modern Approach.” 4<sup>th</sup> ed. Cengage, p. 208.

<sup>185</sup> *See* Rosenthal Deposition Vol. 2, 509:3-509:9.

<sup>186</sup> *See* Cutler Deposition Vol. 2, 545:14-546:1.

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**Exhibit 25: Professor Rosenthal's Table 5, with 90% and 95% Prediction Intervals Added****Notes:**

1. Prediction intervals are asymmetric about the point estimate due to Professor Rosenthal's modeling of opioid shipments on the logarithmic scale, rather than the unit scale.
2. Professor Rosenthal's indirect model relies strictly on 1997 county-level data. Prediction intervals are calculated for 1998 – 2016 by assuming that the standard error of the forecast grows proportionally to the square root of the difference in years from the forecast period to 1997. This assumption is based in part on the presence of a unit root in Professor Rosenthal's shipments data. *See, e.g.,* Pindyck, Robert S. and Daniel L. Rubinfeld. (1997). *Econometric Models and Economic Forecasts*. 4<sup>th</sup> ed. Boston, MA: McGraw-Hill/Irwin; Chapter 16.

**Sources:**

1. Rosenthal Report, Table 5 and supporting materials.
129. Exhibit 25 demonstrates that the observed, actual world opioid shipments lie within the 95% prediction interval of Professor Rosenthal's but-for opioid shipments for all years and within the 90% prediction interval for all but three years. In other words, when uncertainty is

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

considered, Professor Rosenthal's indirect model fails to show that a portion of the actual world, observed shipments are excess.<sup>187</sup>

**6. Professor Rosenthal does not calculate but-for MMEs for the Bellwethers, which introduces uncertainty to Professor Cutler's estimates**

130. Professor Rosenthal's model can be used to calculate excess MMEs at the county level. However, she does not present the results of her indirect model for the Bellwethers. Exhibit 26 shows that the predicted but-for MMEs in 1997 for both Cuyahoga and Summit County differ from actual values. This means there is a portion of opioid shipments that are unexplained by Professor Rosenthal's indirect model in the year prior to the start of the Alleged Conduct, i.e. the 1997 baseline. This indicates Professor Rosenthal's excess MME estimates in subsequent periods for Cuyahoga and Summit County might be unreliable.
131. Exhibit 26 also shows that the indirect model predicts an excess MME share of [REDACTED] for Cuyahoga County and [REDACTED] for Summit County from 1997-2016, both lower than the average estimate of [REDACTED] across all counties that Professor Rosenthal reports. The average estimate of [REDACTED] however, is used by Professor Cutler in his analysis of shipments due to the Alleged Conduct, instead of the more specific numbers for the Bellwethers.<sup>188</sup>

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<sup>187</sup> I later apply the same methodology to the predictions generated by Professor Cutler's indirect regression models. I demonstrate that the predicted, but-for opioid mortality rates estimated by Professor Cutler do not significantly differ from actual world, observed mortality rates.

<sup>188</sup> I also calculate prediction intervals following the same methodology for Summit and Cuyahoga county for the three measures used in Professor Rosenthal and Professor Cutler's indirect models. The results demonstrate that that actual values lie within the prediction intervals of Professors Rosenthal and Cutler's but-for results for shipments and all-opioid mortality rates. The results are ambiguous for Professor Cutler's model of the illicit opioid mortality rate. See Cantor supporting materials.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 26: Professor Rosenthal's Indirect Model Result for the Bellwethers**

Year	Cuyahoga County			Summit County		
	Total MME (MM)	Excess MME (MM)	Excess Share	Total MME (MM)	Excess MME (MM)	Excess Share
1997	173	-13	-7.5%	81	18	21.8%
1998	182	-23	-12.8%	94	14	15.2%
1999	216	1	0.5%	119	42	35.0%
2000	270	45	16.8%	162	74	45.7%
2001	305	70	23.1%	181	90	49.9%
2002	350	119	33.9%	212	117	55.0%
2003	407	170	41.7%	261	160	61.2%
2004	439	184	41.9%	284	179	63.0%
2005	469	209	44.5%	295	190	64.4%
2006	517	258	49.9%	330	220	66.8%
2007	570	299	52.4%	359	240	66.9%
2008	610	333	54.6%	360	244	67.8%
2009	676	407	60.3%	383	262	68.4%
2010	707	415	58.7%	423	302	71.5%
2011	726	431	59.4%	426	303	71.2%
2012	677	376	55.5%	392	276	70.4%
2013						
2014						
2015						
2016						
Total						

Sources: Rosenthal Report, supporting materials.

## V. Expert Report of Professor Cutler

132. Professor Cutler's framework for estimating the share of harm due to the Alleged Conduct follows a three-step methodology. The first step estimates the share of harms attributable to opioids for five divisions of the Track 1 Jurisdictions: (1) criminal activity, (2) addiction and mental health activity, (3) children and family services, (4) juvenile court activity, and (5) medical examiner activity.<sup>189</sup> Professor Cutler then uses regression analysis to estimate the impact of opioid shipments due to the Alleged Conduct on mortality. He justifies the focus on mortality due to the availability of opioid-related mortality information to quantify harm due to opioid shipments.<sup>190</sup> To determine the share of harms incurred by Cuyahoga and Summit Counties due to the Alleged Conduct, Professor Cutler incorporates the estimated

<sup>189</sup> See Cutler Report, at ¶ 20, p. 10.

<sup>190</sup> Professor Cutler adjusts the mortality rate data to better account for unspecified drugs overdoses using the methodology of Christopher Ruhm. See Cutler Report, at ¶¶ 47-48, pp. 28-29. See also Data Appendix, pp. 1-9.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

proportion of excess shipments for an average county from Professor Rosenthal and applies the framework shown in Exhibit 27.<sup>191</sup>

**Exhibit 27: Professor Cutler's Framework<sup>192</sup>**

$$\begin{aligned}
 & \textit{Share of Harms Attributable to Defendants' Misconduct} \\
 &= \textit{Share of Harms Attributable to Opioids} \\
 &\quad \times \textit{Share of Opioid Harms Attributable to Opioid Shipments} \\
 &\quad \times \textit{Share of Opioid Shipments Due to Defendants' Misconduct}
 \end{aligned}$$

**A. Professor Cutler's analysis of harms suffers from inappropriate generalities based on mortality data and inconsistencies with Plaintiffs' theory**

**1. Professor Cutler inappropriately uses mortality as a proxy to estimate a variety of disparate harms due to the Alleged Conduct**

133. Professor Cutler estimates the impact of the Alleged Conduct on opioid harms from his analysis of opioid-related mortality. To find impact, he is essentially estimating the product of the second and third factor in the framework above. He assumes this is a reliable proxy for the required impact proportions for a broad set of heterogeneous municipality agencies and organizations ("divisions") in the Track 1 Jurisdictions, as demonstrated in Exhibit 28. In using one constant measure of impact, Professor Cutler fails to account for the obvious differences in harms across the allegedly damaged divisions. Under this framework, the impact proportion of observed increases in deaths due to illicit fentanyl, for example, is used to approximate the impact on Juvenile Court case activity attributable to the Alleged Conduct.<sup>193</sup> Professor Cutler provides no complete analysis proving a uniform relationship

<sup>191</sup> See Cutler Report, at ¶ 104. Professor Cutler runs parallel analyses using Professor Rosenthal's direct and indirect model results, *see also* Cutler Report, at p. 62, Table III. Table III.9 and Appendix II.K., p. 63. Estimates shown rely on Rosenthal's direct model results; however, an alternate version of Professor Cutler's approach using Rosenthal's indirect model results is presented in Appendix III.K.

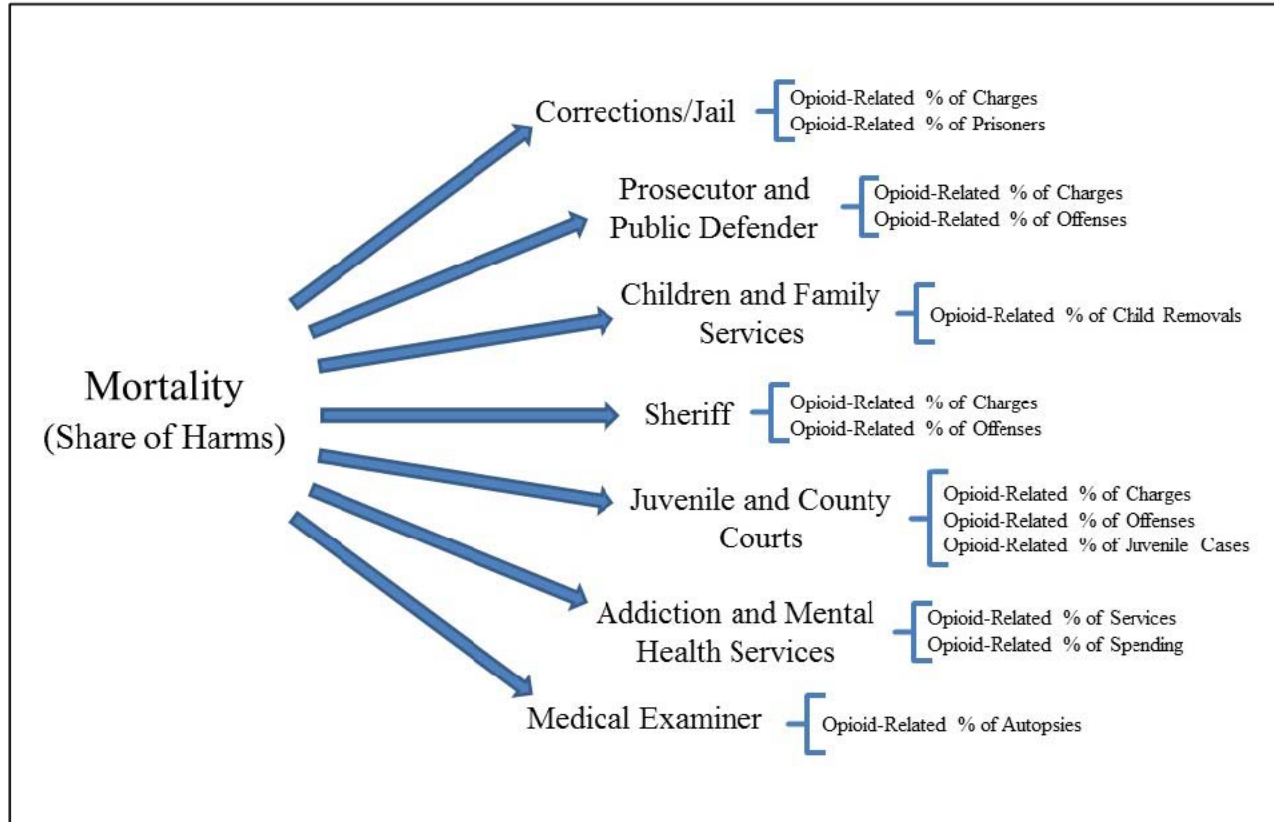
<sup>192</sup> See Cutler Report, at ¶ 24, p. 12.

<sup>193</sup> See Cutler Report, at ¶ 45.



## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

between opioid-related mortality and all other categories of harm that he addresses, undermining the assumptions fundamental to his framework overall.<sup>194</sup>

**Exhibit 28: Professor Cutler's Metrics of Harm<sup>195</sup>**

134. In defense of using a proxy for impact based on opioid-related mortality, Professor Cutler states that he is “using mortality as an estimate of the share of the harms that are due to shipments of opioids, so I’m going to assume that that share of the harms is due to opioids, and that’s a fairly -- obviously a very severe form of harm.”<sup>196</sup> Without testing the applicability of this proxy, Professor Cutler has no way of knowing that it reliably measures impact to the other divisions.<sup>197</sup> This is unlikely to be the case as Professor Cutler applies

<sup>194</sup> Note, Professor Cutler performs a “confirmatory” regression of property and violent crime rate on average shipments across counties to confirm his framework for estimating impacts. However, this analysis excludes both Cuyahoga and Summit County and, therefore, fails to confirm his methodology for the Track 1 Jurisdictions. See Cutler Report, at ¶¶ 126-133 and Appendix III.L.

<sup>195</sup> See Cutler Report, at ¶ 20, pp. 10-11 and Table III.1.

<sup>196</sup> See Deposition of David Cutler, Ph.D., Vol. 2, *In Re National Prescription Opiate Litigation* (Apr. 27, 2019), (“Cutler Deposition Vol. 2”), at 454:10-15.

<sup>197</sup> See Cutler Deposition Vol. 2, at 457:9-457:12



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

his impact proxy to categories as diverse as autopsies and juvenile court activity due to drug possession offenses.

**2. Plaintiffs' shipment-to-harms causation theory is inconsistent with the actual data for the Track 1 Jurisdictions**

135. Professor Gruber argues that counties receiving higher licit shipments per capita from 1997 to 2010 experienced higher opioid mortality rates. He further indicates that “mortality from heroin/fentanyl accelerated more in the high shipment counties after 2010.”<sup>198</sup> The sharp increase in illicit mortality from 2013 to 2016, however, is observed in both high and low shipment counties.<sup>199</sup> Such observations suggest the presence of confounding factors unrelated to the level of licit shipments on opioid-related mortality.
136. Similarly, the observed rates for the Track 1 Jurisdictions challenge a simple shipment-to-harms theory.<sup>200</sup> As shown in Exhibit 29 below, Summit County experienced substantially higher shipments than Cuyahoga County throughout the full time period, and slightly higher than even the national average for 1997 to 2012. Under Plaintiffs' theory, Summit County should exhibit opioid-related mortality rates *higher* than Cuyahoga County. Exhibit 30, however, shows that Summit mortality rates were at or below Cuyahoga's mortality until 2014.<sup>201</sup> Importantly, the failure to find a higher mortality rate in Summit indicates that other factors besides shipments are important to understand causality.

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<sup>198</sup> See Gruber Report, at ¶¶ 84-85, p. 58-59.

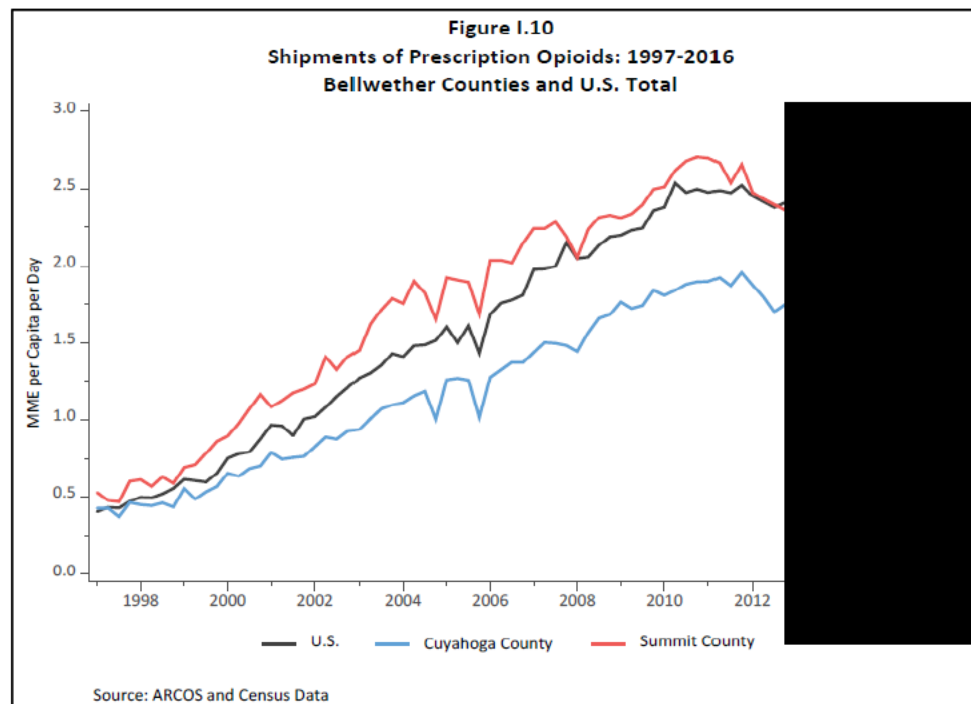
<sup>199</sup> See Gruber Report, at Figure I.19, p. 60.

<sup>200</sup> See e.g., The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al., "Second Amended Corrected Complaint, Demand for Jury Trial," Case No. 1:17-md-02804, filed May 30, 2018, ¶ 645.

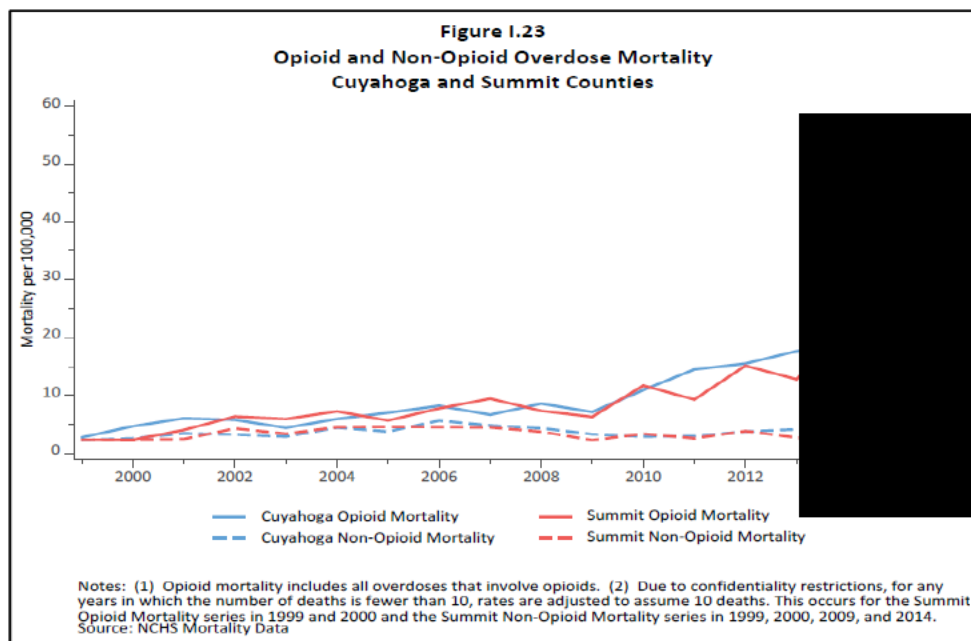
<sup>201</sup> Professor Gruber did not perform any analysis on the difference in observed mortality between the Track 1 Jurisdictions in developing his shipment-to-harms theory. See Deposition of Jonathan Gruber, Ph.D., *In Re National Prescription Opiate Litigation* (Apr. 25, 2019), (“Gruber Deposition”), 438:1-13.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 29: Reproduction of Professor Gruber's Figure I.10<sup>202</sup>**



**Exhibit 30: Reproduction of Professor Gruber's Figure I.23<sup>203</sup>**



<sup>202</sup> See Gruber Report, at Figure I.10, p. 43.

<sup>203</sup> See Gruber Report, at Figure I.23, p. 76.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**3. Professor Cutler has not considered that the harm incurred by the Track 1 county Plaintiffs is different from the former Track 1 city Plaintiffs**

137. Professor Cutler has examined harms at the county level, but he has not adjusted for harms incurred by *the city* separately from those occurring *outside* the city. My analysis of the opioid overdose autopsies in the Track 1 Jurisdictions' Medical Examiner data indicates that approximately [REDACTED] are associated with an address in the cities of Cleveland or Akron.<sup>204</sup>
138. Professor Cutler's measured mortality harms and related analysis of impact are likely based on deaths and shipments inflated by the city data. This is disregarded in the estimation of his impact proxy, likely attributing a portion of city-specific harms to county-specific relationships. Moreover, when the proxy is applied to other county divisions where city and county harms are distinct, Professor Cutler would measure additional impacts.

**4. Professor Cutler fails to demonstrate that individuals receiving prescription opioids dispensed from pharmacies are the individuals overdosing from licit and illicit opioids**

139. Professor Cutler's direct model shows an association between shipments and mortality rates, but it does not explicitly model how changes in the rates are caused. Importantly, neither Professor Cutler nor Professor Gruber provide evidence that those receiving prescription opioids shipped to retail dispensers (e.g., pharmacies, grocery stores) are the same as individuals who overdose from opioids.<sup>205</sup> As a result, an analysis to address causality must examine differences in the respective populations and what, if any, other factors affect the overdose behavior.
140. A comparison of individuals receiving a prescription opioid from a retail dispenser and individuals overdosing from opioids demonstrates important distinctions between these populations. Exhibit 31 illustrates Cuyahoga and Summit County's demographics associated with prescriptions as compared to overdoses, indicating that while [REDACTED] of overdose deaths

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<sup>204</sup> See Cantor supporting materials.

<sup>205</sup> Professor Gruber acknowledges the inconsistency between individuals most often receiving prescription opioids and individuals abusing heroin, rationalizing, "When you take a set of data, which are showing a relationship, that does not mean that every element of the data perfectly conforms with that relationship." See Gruber Deposition, 397: 13-17, April 25, 2019.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

are young adult males (e.g., ages 25-34), this demographic accounts for only 4% of patients receiving an opioid prescription.<sup>206</sup> Similarly, females aged 45-54 are the highest proportion of patients receiving an opioid prescription, but fall far behind males in the proportion of opioid deaths.

**Exhibit 31: Individuals Receiving Prescription Opioids vs. Individuals Overdosing Due to All Opioids**

Sex	Age	% of Bellwether Population	% of Opioid Patients	% of Opioid Deaths	Population Mismatch
Male	45-54				
Male	25-34				
Male	35-44				
Male	55-64				
Female	45-54				
Female	25-34				
Female	35-44				
Male	15-24				
Female	55-64				
Female	15-24				
Male	65-74				
Female	65-74				
Female	75-84				
Female	00-04				
Male	75-84				
Female	05-14				
Female	85 and over				
Male	00-04				
Male	05-14				
Male	85 and over				

141. There is information indicating that opioid abusers are obtaining opioids from patients who are also their friends or relatives.<sup>207</sup> Exhibit 32 is a reproduction from the CEA report showing that such sources (i.e. friends or relatives) are relevant for 50% of the users.<sup>208</sup> Importantly, monitoring or preventing these types of transfers would be essentially

<sup>206</sup> Data on patients receiving opioids is sourced to Plaintiff Beneficiary claims data (produced April 12, 2019), and opioid-related overdose deaths are based on Cuyahoga and Summit County's Medical Examiner data. Demographic estimates for Cuyahoga and Summit are based on census population statistics produced in "Shared\_data" folder of Plaintiff Experts' supporting materials. See CUYAH\_000099975.xlsx and SUMMIT\_000087427.xlsx.

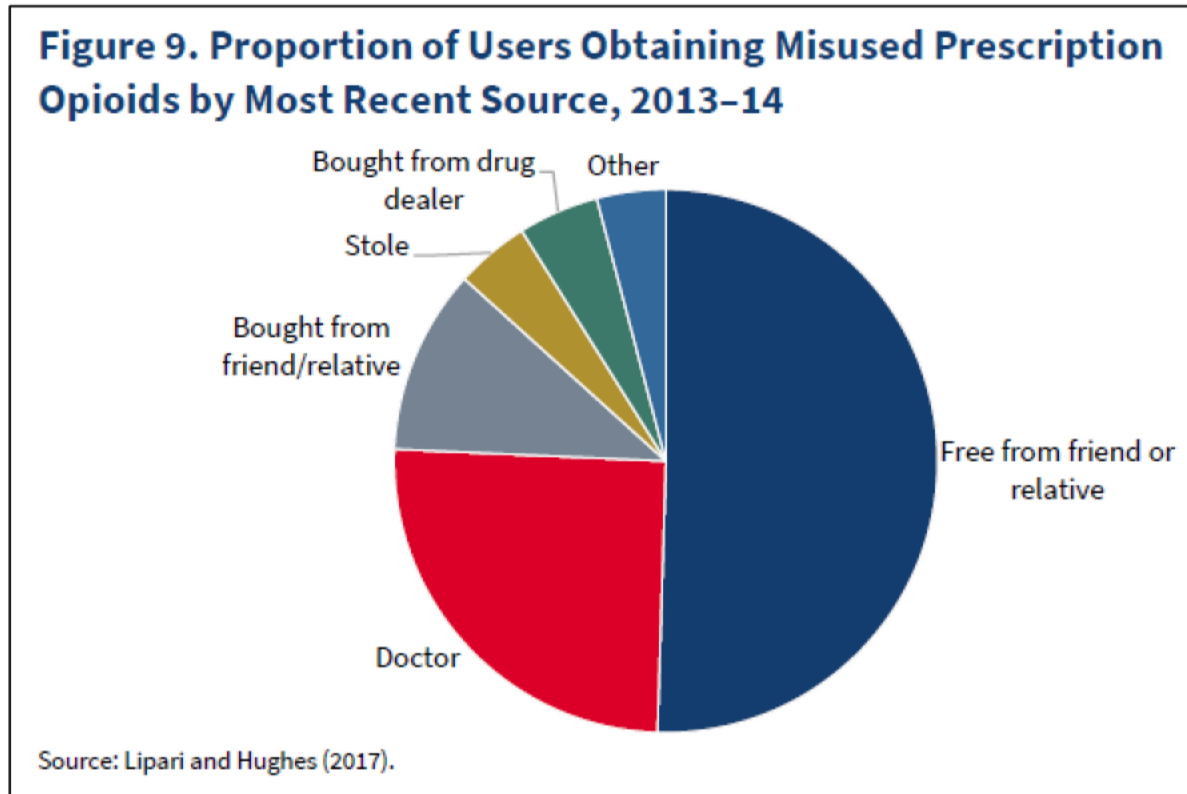
<sup>207</sup> See CEA Report, at p. 21.

<sup>208</sup> See CEA Report, at p. 20, Figure 9, citing Lipari, R., and A. Hughes. "How People Obtain the Prescription Pain Relievers They Misuse." *CBHSQ Report*, (2017), available at [https://www.samhsa.gov/data/sites/default/files/report\\_2686/ShortReport-2686.html](https://www.samhsa.gov/data/sites/default/files/report_2686/ShortReport-2686.html).

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

impossible for defendant manufacturers. Moreover, these diversions have not been isolated or controlled for in Professor Cutler’s analysis of impacts.<sup>209</sup>

**Exhibit 32: Opioid Abusers by Most Recent Source<sup>210</sup>**



142. Professor Cutler recognizes that shipments and consumption are different factors important for understanding causality yet he effectively treats them as the same construct in his analysis.<sup>211</sup>

**5. Professor Cutler assumes the increase in illicit opioid mortality is due to the Alleged Conduct, but does not adequately consider but-for harms resulting from illicit opioids**

143. Professor Cutler relies on Professor Gruber’s report to establish the alleged late-2010 break in the opioid epidemic and support his use of a direct model (pre-2010) and indirect model (post-2010). Professor Cutler employs these two methods to estimate the alleged effect of

<sup>209</sup> See Cutler Report, at Appendix III.J.

<sup>210</sup> See CEA Report, at Figure 9, p. 20.

<sup>211</sup> See Cutler Report, at ¶¶ 73-74, pp. 41-42.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

prescription opioid shipments on opioid-related mortality (which includes both prescription and illicit opioids).<sup>212</sup> Essentially, the theory is as follows: The prescription opioid industry oversupplied the population.<sup>213</sup> This allegedly generated a high stock of prescription opioid addicts by late 2010. The oversupply caused external actors to place controls on prescription opioids, which decreased the supply of prescription opioids post-2010. Subsequently, the stock of prescription opioid addicts theoretically turned to illicit opioids. Therefore, according to Plaintiffs' theory, the prescription opioid industry allegedly caused an increase in prescription opioid mortality and an increase in illicit opioid mortality.

144. However, this theory of illicit mortality post-2010 fails to prove that the increased use of illicit fentanyl stems from individuals who previously used prescription opioids. In addition, this posited casual chain is confounded if the sharp rise in illicit fentanyl overdoses reflects an increase in *supply* rather than an increase in *demand*. Professor Cutler does not consider sources of illicit supply, such as the role of criminal organizations in driving illicit opioid volume. A brief history of illicit fentanyl use shows that (1) supply-side factors (e.g., low cost of production) provide incentives to increase fentanyl production, and (2) illicit fentanyl consumption (inferred from overdoses) does not fully reflect demand for illicit fentanyl.
145. After 2013, I understand that illegal drug traffickers began incorporating fentanyl into the illicit U.S. drug supply through imports, mainly from China and Mexico.<sup>214</sup> Fentanyl is a "low-cost and high potency alternative to heroin", and therefore, drug dealers blend it with other illicit drugs (e.g., heroin, cocaine, counterfeit prescription opioids) in order to lower costs and increase margins.<sup>215</sup> Driven by a "desire to increase margins on and increase the

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<sup>212</sup> See Cutler Report, at ¶¶ 68-69, p. 78; Gruber Report, at ¶ 88 p. 32,

<sup>213</sup> See e.g., The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al., "Second Amended Corrected Complaint, Demand for Jury Trial," Case No. 1:17-md-02804, filed May 30, 2018, ¶ 645.

<sup>214</sup> See Gruber Report, at ¶ 55; DEA Intelligence Brief, "Counterfeit Prescription Pills Containing Fentanyls: A Global Threat, DEA-DCT-DIB-021-16," July 2016, *available at* [https://content.govdelivery.com/attachments/USDOJDEA/2016/07/22/file\\_attachments/590360/fentanyl%2Bpills%2Breport.pdf](https://content.govdelivery.com/attachments/USDOJDEA/2016/07/22/file_attachments/590360/fentanyl%2Bpills%2Breport.pdf), at p. 7.

<sup>215</sup> See Gruber Report, at ¶¶ 55 and 58-59. DEA Intelligence Brief, "Counterfeit Prescription Pills Containing Fentanyls: A Global Threat, DEA-DCT-DIB-021-16," July 2016, *available at* [https://content.govdelivery.com/attachments/USDOJDEA/2016/07/22/file\\_attachments/590360/fentanyl%2Bpills%2Breport.pdf](https://content.govdelivery.com/attachments/USDOJDEA/2016/07/22/file_attachments/590360/fentanyl%2Bpills%2Breport.pdf), p. 7.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

sales of heroin, drug dealers sometimes go as far as to substitute heroin for fentanyl all together.<sup>216</sup>

146. Generally, fentanyl is not a drug product demanded by consumers, and “its emergence is not driven by consumers’ demand for a new type of drug.”<sup>217</sup> Fentanyl first entered the U.S. drug supply through heroin, and oftentimes, heroin users do not know that fentanyl has been used as an adulterant and mixed with their drug supply.<sup>218</sup> Many heroin users recognize the dangers associated with fentanyl and have no desire to use it.<sup>219</sup> Importantly, Professor Cutler does not consider how the consequences of illicit fentanyl disproportionately affect the outcome of interest (i.e. overdose mortality). Exhibit 33 shows the sharp increase in fentanyl-related deaths associated with concomitant drugs (e.g., cocaine), evidencing the growing prevalence of drug dealers blending their products with this cheaper yet more lethal illicit substance. This information is consistent with the conclusion that consumption of illicit fentanyl (as measured by mortality) is coincident with the demand for other drugs. Moreover, Professor Cutler has not considered that deaths due to increased *risk of fatality* due to laced fentanyl is separate and distinct from an increased *demand* for illicit fentanyl.

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<sup>216</sup> See Gruber Report at ¶¶ 59 and 60.

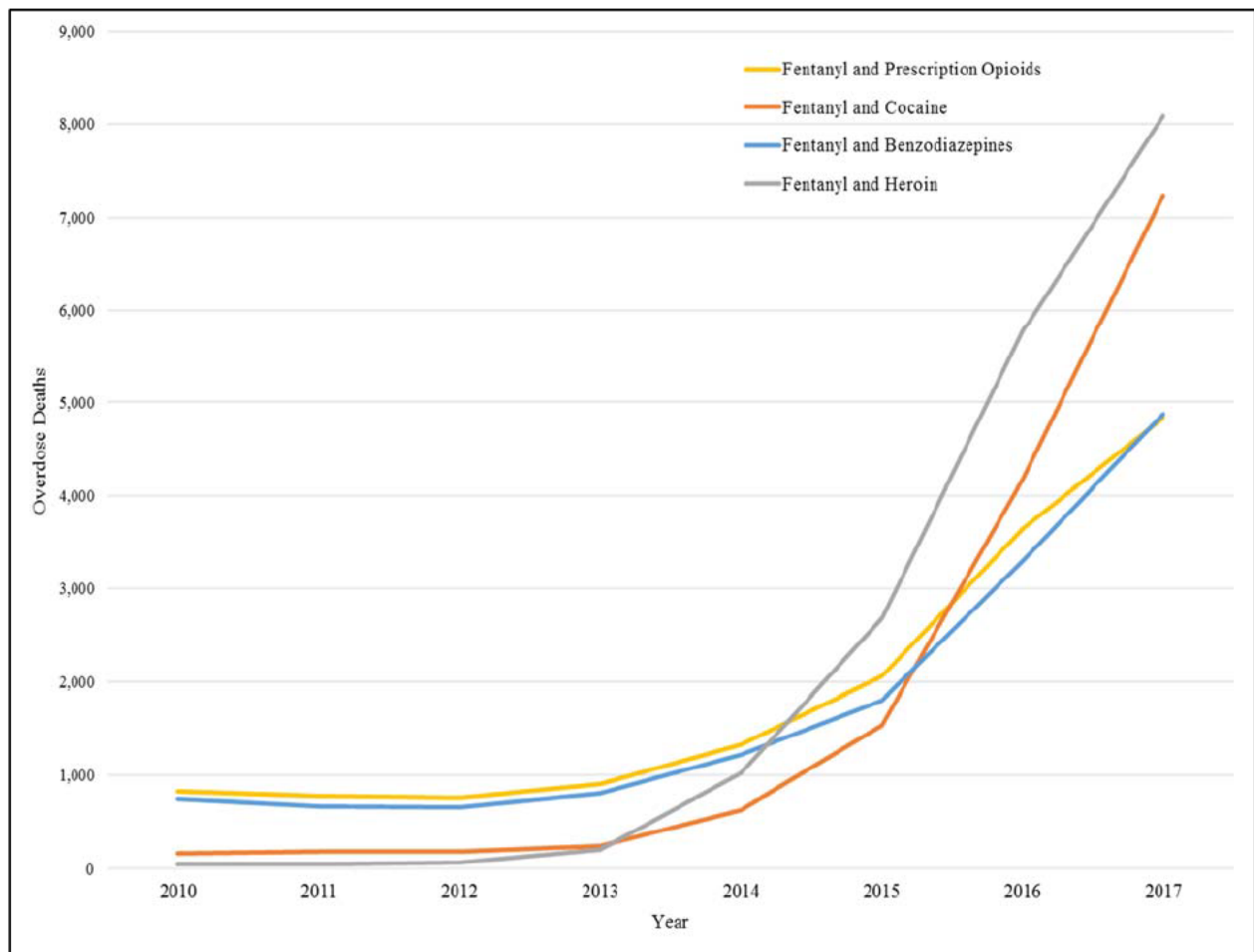
<sup>217</sup> The supply-driven fentanyl epidemic is further supported by the epidemic’s geographic variation. Since at least the 1990s, the heroin market has been divided between powdered heroin east of the Mississippi and black tar heroin west of the Mississippi. It is easier to substitute fentanyl for powder heroin, and as a result, fentanyl’s “emergence after 2013 was even more highly concentrated in the eastern U.S., where powdered heroin was more prevalent.” See Gruber Report, at ¶¶ 54 and 62.

<sup>218</sup> See Gruber Report, at ¶ 58, citing US Department of Justice Drug Enforcement Agency, “2017 National Drug Threat Assessment,” available at [https://www.dea.gov/sites/default/files/2018-07/DIR-040-17\\_2017-NDTA.pdf](https://www.dea.gov/sites/default/files/2018-07/DIR-040-17_2017-NDTA.pdf), p. 59.

<sup>219</sup> See Gruber Report, at ¶¶ 60 and 61, citing US Department of Justice Drug Enforcement Agency, “2017 National Drug Threat Assessment,” available at [https://www.dea.gov/sites/default/files/2018-07/DIR-040-17\\_2017-NDTA.pdf](https://www.dea.gov/sites/default/files/2018-07/DIR-040-17_2017-NDTA.pdf), p. 59.



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 33: Trends in Fentanyl-Related Overdose Deaths<sup>220</sup>**

147. In conclusion, other information, as well as the trend illustrated above, indicate that the growth in illicit fentanyl mortality reflects the substance's increased likelihood to cause an overdose more so than a shift in demand to consume it.<sup>221</sup> Professor Cutler has not isolated the effects of demand for illicit drugs and their consequent risks not due to the Alleged Conduct that would cause overdoses in the but-for world regardless of Defendants' actions.
148. As prefaced above, another factor affecting the increasing abuse of illicit opioids not due to the Alleged Conduct is that fentanyl is relatively inexpensive and its increased supply has substantially lowered the price of illicit drugs.<sup>222</sup> Previously, Professor Cutler has

<sup>220</sup> Overdose data is based on Multiple Cause of Death data from CDC Wonder, available at <https://wonder.cdc.gov/mcd-icd10.html>

<sup>221</sup> See Gruber Report, at ¶¶ 60 and 61. See also US Department of Justice Drug Enforcement Agency, "2017 National Drug Threat Assessment," available at [https://www.dea.gov/sites/default/files/2018-07/DIR-040-17\\_2017-NDTA.pdf](https://www.dea.gov/sites/default/files/2018-07/DIR-040-17_2017-NDTA.pdf), p. 59.

<sup>222</sup> See e.g., CEA Report, at p. 1.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

acknowledged the effect of price on illicit drug use, attributing a share of the 1995-96 drug epidemic in South Boston to a decrease in the price of heroin.

*“Q. You opined or you wrote that there was a heroin -- strike that. You wrote that there was a drug epidemic in 1995 and 1996 in South Boston that included the use of heroin, right?”*

*A. It was terrible. Yes, there was.*

*Q. And you attributed one of the -- strike that. You identified one of the reasons for the epidemic was a decrease in the price of heroin. Do you see that?”*

*A. Yes, that's correct.*

*Q. And you understand that there was generally a decrease in the price of heroin in the United States in the 2010s, right?”*

*A. Yes, that's correct, there was a decrease in the price of heroin.*

*Q. And you haven't controlled for the decrease in the price of heroin in connection with your regression models, correct?”*

*A. Actually, I don't think that it would be appropriate to control for the price of heroin in those models.”<sup>223</sup>*

149. Professor Cutler’s calculation of the share of harms related to opioids does not attempt to disentangle the effects of licit versus illicit opioid abuse. To estimate the percentage of medical examiner activity attributable to opioids, he identifies autopsies for overdose deaths associated with *any* opioid in Cuyahoga and Summit Counties.<sup>224</sup> According to the Medical Examiner data, approximately two-thirds of autopsies performed from 2006 to 2017 include a cause of death not associated with a licit opioid.<sup>225</sup> Because Professor Cutler’s estimated percentage of Medical Examiner activity fails to adjust for overdoses due to supply shifts in fentanyl or increased consumption risks that likely would have occurred in the but-for world, it overstates the impact of the Alleged Conduct on opioid-related mortality.

**B. Professor Cutler’s direct model examines only the change between two periods of time, excluding effects that occur in the period in between**

150. Professor Cutler’s direct model estimates the impact of shipments on mortality entirely based on one observation per county: the *change* in mortality between 1993-95 and 2009-10.<sup>226</sup>

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<sup>223</sup> See Cutler Deposition Vol. 1, at 320:4-321:10.

<sup>224</sup> Professor Cutler relies on Medical Examiner data produced by Cuyahoga and Summit Counties, *see* CUYAH\_000099975.xlsx and SUMMIT\_000087427.xlsx.

<sup>225</sup> Licit opioids are identified as any opioid not flagged as heroin or fentanyl, thus this share of licit opioid overdoses is likely overly inclusive.

<sup>226</sup> Professor Cutler’s report does not indicate why he chose a three-year average in the baseline and a two-year average for the end of the period.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

By design, Professor Cutler disregards how mortality rates respond to other factors from 1996 to 2008 and, therefore, does not consider all information in estimating his model. My analysis shows that when additional information is considered, the results indicate a lower correlation between shipments and mortality, if any.<sup>227</sup> However, even when considering the temporal variation in Professor Cutler's model, only a limited set of information is considered (i.e. demographic and socio-economic variables). Thus, it is possible that, had omitted factors been included, he would have found no reliable effect of shipments on mortality. As one example of this concern, Exhibit 34 below presents regression results when increasing the sample to include annual county-level observations for the full time period. The impact of shipments per capita per day coefficient is [REDACTED] approximately one-third less than Professor Cutler's result of [REDACTED].<sup>228</sup>

151. In addition, if Professor Cutler's model is used to simulate the mortality rates for the Track 1 Jurisdictions, it over predicts the post-period mortality rates for Summit by [REDACTED] and under predicts the rates for Cuyahoga by [REDACTED].<sup>229</sup> These errors are larger than typically tolerated for reliable estimates of economic outcomes.

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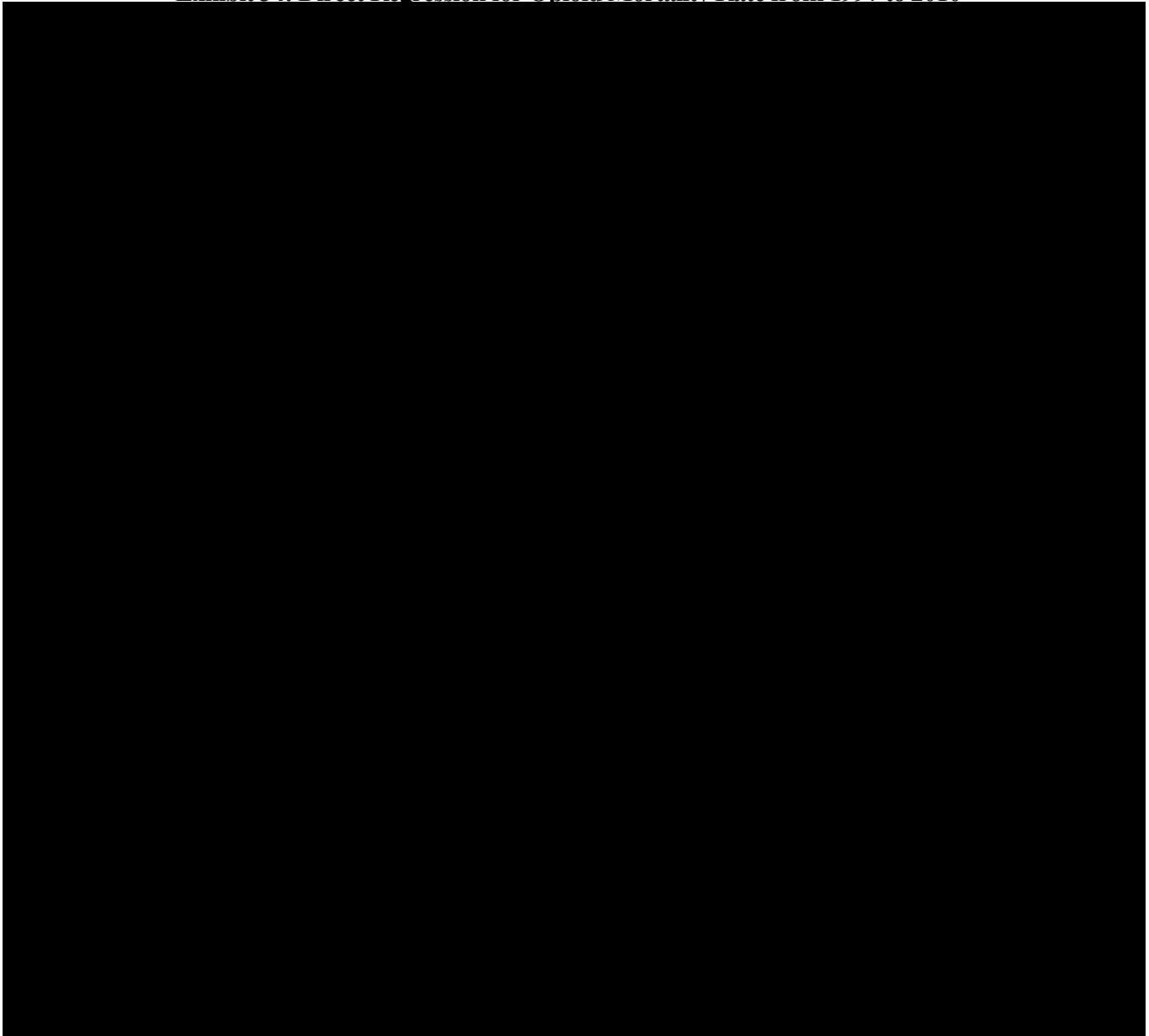
<sup>227</sup> This approach employs a panel dataset allowing for cross-sectional and time series variation.

<sup>228</sup> See Cutler Report, at Appendix III.H.

<sup>229</sup> See Cantor supporting materials.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 34: Direct Regression for Opioid Mortality Rate from 1997 to 2010**



**Source:** Cutler Report, supporting materials.

152. Additionally, without justification Professor Cutler selects 1993-1995 as the baseline for his long difference model. There is information indicating reliability issues with the mortality data in the 1993-1995 period.<sup>230</sup> This likely suppresses the “baseline” mortality rates used in the estimations not sufficiently addressed by Professor Cutler in his adjustments to the data because he does not present supporting guidance to ensure his baseline are accurate. Thus

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<sup>230</sup> See Expert Report of Rob Lyerla, Ph.D., *In Re National Prescription Opiate Litigation* (May 10, 2019) (“Lyerla Report”).

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

it is entirely possible that Professor Cutler’s baseline mortality rate is biased downward due to measurement error, resulting in a larger change between 1993-1995 and 2009-2010 and a larger result for his estimated impact.

153. Overall, Professor Cutler’s direct approach is inappropriate in this matter because his long difference model will not reflect short term but import implications for how the opioid crisis evolved. Moreover, the approach might attribute the influence of important omitted factors to modeled factors and result in biased findings.

**C. Professor Cutler’s modeling of harms ignores benefits from reducing pain**

154. Professor Cutler’s framework quantifies societal *harms* due to opioid use.<sup>231</sup> This analysis is missing an assessment of the societal *benefits* of opioid use for chronic pain treatment—specifically quantification of these benefits. Professor Cutler fails to address benefits of medical opioid use observed in the actual world as an offset to harms in the but-for world. Absent prescription opioids (i.e. “but-for” world), it is probable that negative consequences would have occurred due to a lack of effective treatment for pain.<sup>232</sup> These negative outcomes were avoided in the actual world, and, therefore, must be treated as countervailing risks in the but-for world.<sup>233</sup>
155. Professor Cutler’s estimation of harms does not make any attempt to quantify the countervailing risks in his but-for scenario.<sup>234</sup> In modeling damages incurred in the actual world, it is necessary to consider both costs and *benefits* that one would not expect in the but-for world. Professor Cutler asserts mortality appropriately measures harm, but admits that “any impact that was favorable would be captured only to the extent that it influenced mortality.”<sup>235</sup> For example, absent prescription opioids, individuals with chronic pain would experience higher levels of pain, and impeding their productivity in the workplace.<sup>236</sup>

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<sup>231</sup> See Cutler Report, at ¶ 16.

<sup>232</sup> Professor McGuire recognizes the positive externalities generated from prescription opioids as an offset to costs. See McGuire Public Nuisance Report, at ¶¶ 23-24, 14; R., Rubin. “Limits on Opioid Prescribing Leave Patients With Chronic Pain Vulnerable,” JAMA, (Apr. 29, 2019).

<sup>233</sup> See, e.g., Regulatory Analysis, Circular A-4 (Sep. 17, 2003), at p. 26.

<sup>234</sup> See Cutler Deposition Vol. 1, 150:4-154:17.

<sup>235</sup> See Cutler Deposition Vol. 1, 154:8-17.

<sup>236</sup> As discussed in the McGuire Public Nuisance Report, see ¶¶ 73, p. 41, studies find a negative impact of pain on productivity and labor. See e.g., D.J. Gaskin and P. Richard, “The Economic Cost of Pain in the United States,” *The Journal of Pain*, 13(8), 2012, pp. 715-724. C. Garthwaite, “The economic benefits of pharmaceutical innovations:

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

Professor McGuire acknowledges, “prescription opioids, when used appropriately for treatment of pain, may increase labor force participation and employment for pain-afflicted individuals.”<sup>237</sup> While confounding events in the actual world make difficult the quantification of the effect of medical prescription opioid use on mortality, productivity, and quality of life, the externalities of untreated pain cannot be disregarded in the but-for world for the purposes of a reliable estimate of the net impacts.

156. Professor Cutler’s disregard of the avoided harms in his assessment of impact due to the Alleged Conduct to the counties leads to an overestimate of the true proportions eventually used and applied by Professor McGuire.

**D. Professor Cutler creates variables to address missing data without sufficient evidence**

157. At many times in his analysis, Professor Cutler requires information that is missing from the available sources relied upon. In these numerous instances, he resorts to speculation, extrapolation, and data creation. In some cases, the amount of information he has for addressing data gaps is substantially inadequate for reliable inference. Exhibit 35 shows the instances where Professor Cutler has attempted to fill data gaps. I explain the implications below.

**Exhibit 35: Professor Cutler’s Data Extrapolations for Share of Opioid-Related Harms Estimates**

Division	Data Source	Available Years	Extrapolated Years	Variable	Application
Criminal Activity	Survey of Inmates in Local Jails	2002	2006-2017	% Drug-induced crimes	Share of crimes committed due to drugs
Criminal Activity				% Drug-related crimes	Share of crimes committed under the influence of drugs
Juvenile Court Activity					Share of drug-related juvenile criminal charges
Criminal Activity	DEA National Forensic Laboratory Information System	2007-2017	2006	# Opioid seizures	Share of opioid-related drug crimes
Juvenile Court Activity					Share of opioid-related juvenile drug crimes
Criminal Activity	National Survey on Drug Use and Health	2006-2013	2014-2017	# individuals with OUD / # individuals with illicit SUD	Share of drug-related/induced crimes committed due to opioids
Juvenile Court Activity					Share of drug-related juvenile criminal charges due to opioids
Children’s and Family Services	Public Children Services Association of Ohio	2015	2006-2014; 2016-2017	% Child removals with parental opioid use	Share of Children’s and Family Services harms due to opioids
Juvenile Court Activity					# Opioid-related removal cases in juvenile court
Juvenile Court Activity	Summit Court of Common Pleas	2014-2016	2006-2013; 2017	# Charges by type of crime	Summit juvenile criminal charges
Criminal Activity	Cuyahoga County Prosecutor’s Office	2009-2017	2006-2008	# Adult charges by offense	Cuyahoga criminal offenses

The case of cox-2 inhibitors,” *American Economic Journal: Applied Economics*, 2012, 4(3), pp. 116–137. A. Butikofer and M. M. Skira, “Missing Work is a Pain: The Effect of Cox-2 Inhibitors on Sickness Absence and Disability Pension Receipt,” *Journal of Human Resources*, 2018, 53(1), pp. 71-122.

<sup>237</sup> See McGuire Public Nuisance Report, at ¶ 73.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**1. Estimation of the share of opioid-related crime is based on speculation and incomplete data**

158. Professor Cutler’s calculation of criminal activity attributable to opioid shipments involves three steps, each of which suffers from unreliability:

- 1) Total criminal activity by type of crime in Cuyahoga and Summit Counties,
- 2) Share of crimes directly or indirectly motivated by drugs (i.e. “drug-related” crimes), and
- 3) Share of drug-related crimes due to opioids.

159. Due to incomplete data, Professor Cutler relies on several sources to determine the volume of criminal activity for the two counties. Exhibit 36 below is a summary of the categories for which he has attempted to address missing data components.

160. Regarding the categories marked in orange, to estimate criminal activity in Cuyahoga County, Professor Cutler uses 2009-2017 County Prosecutor data and extrapolates 2006-2009 criminal charges and 2006-2008 adult charges.<sup>238</sup>

161. Regarding the yellow category, Professor Cutler must combine data sources for criminal activity in Summit. Professor Cutler combines data from National Incident-Based Reporting System (NIBRS) offenses and BJS Prisoner Statistics.<sup>239</sup> While NIBRS is limited to offenses reported by Summit County, the Prisoner Statistics includes prisoners incarcerated across various regions nationally. By estimating the volume of Summit County’s correctional services (measured by number of prisoners) using BJS’s Prisoner Statistics, Professor Cutler assumes that Summit County’s criminal activity is proportional to the *national* distribution of state prisoners by offense type. This methodology fails to identify harms uniquely incurred by Summit County and instead relies on a profile of national crime. Importantly, because the BJS Prisoner Statistics data is limited to 2006 to 2015, Professor Cutler’s estimates for 2016-2017 are set equal to a single value in 2015. This extrapolation reliant

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<sup>238</sup> Cuyahoga County criminal activity is measured by criminal charges and adult charges. Appendix III.C of the Cutler Report discusses the methodology for extrapolating criminal charges and adult charges. *See* Cutler Report, at Appendix III.C, Panel C1 and Panel D1.

<sup>239</sup> NIBRS contains data on criminal offenses in Summit County reported to FBI UCR program. Bureau of Justice Statistics National Prisoner Statistics includes data on prisoners under state jurisdiction across the nation.



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

on an insufficient number of values potentially leads to a bias of estimated harm and, therefore, lacks reliability.

162. Regarding the blue category, Professor Cutler calculates the share of criminal activity directly or indirectly motivated by drugs for 2006 to 2017 using a single year's data from the 2002 Survey of Inmates in Local Jails (SILJ).<sup>240</sup> This estimation suffers from two forms of potentially substantial error: (1) survey self-reporting bias, and (2) extrapolation based on one observation. Professor Cutler relies on the self-reported 2002 SILJ survey results to calculate the share of drug-related crimes and applies the 2002 percentage to every year for 2006-2017. Professor Cutler presents no support for this extrapolation, but instead “[assumes] that these percentages have not changed.”<sup>241</sup> He combines the percentage of criminal activity directly or indirectly motivated by drugs with other information from the same survey reflecting the share of drug-related crimes in 21 of the 22 crime categories.<sup>242</sup>

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<sup>240</sup> See Bureau of Justice. Survey of Inmates In Local Jails (SILJ). 2002, *available at* <https://www.bjs.gov/index.cfm?ty=dcdetail&iid=274>.

<sup>241</sup> See Cutler Report, at fn 21, p. 19.

<sup>242</sup> Drug crimes are assumed to be 100% related to drugs. Data on illicit drug seizures are used to estimate the share of opioid-related drug seizures. See U.S. Drug Enforcement Administration, Diversion Control Division. 2007-2017, at Table 2: State counts for the most frequently identified drugs, *available at* <https://www.nflis.deadiversion.usdoj.gov/Resources/NFLISPublicResourceLibrary.aspx>.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 36: Reproduction of Professor Cutler's Appendix III.C1-2<sup>243</sup>**

Opioid-Related Percent of Criminal Activity -- Cuyahoga												
	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
<b>PANEL A - OPIOID-RELATED % OF CHARGES (Prosecutor / Public Defender / Sheriff)</b>												
[1] Total Charges Related to Drugs	20,894	20,074	19,254	18,434	18,748	17,608	16,681	16,210	15,403	13,537	14,116	15,266
[2] Total Charges	61,388	59,589	57,790	55,992	57,146	54,348	51,219	50,673	53,887	53,885	54,588	50,955
[3] Drug-Related % of Charges	34.0%	33.7%	33.3%	32.9%	32.8%	32.4%	32.6%	32.0%	28.6%	25.1%	25.9%	30.0%
[4] Total Charges Related to Opioids	3,400	3,273	4,146	4,700	5,482	5,265	5,044	5,097	5,052	4,707	4,942	5,584
[5] Total Charges Related to Drugs	20,894	20,074	19,254	18,434	18,748	17,608	16,681	16,210	15,403	13,537	14,116	15,266
[6] Opioid % of Drug-Related Charges	16.3%	16.3%	21.5%	25.5%	29.2%	29.9%	30.2%	31.4%	32.8%	34.8%	35.0%	36.6%
<b>PANEL B - OPIOID-RELATED % OF ADULT CHARGES (Court of Common Pleas / Jail)</b>												
[1] Total Adult Charges Related to Drugs	20,277	19,476	18,674	17,873	18,157	16,979	15,912	15,023	13,585	11,680	12,161	13,579
[2] Total Adult Charges	57,797	56,091	54,386	52,680	53,721	50,335	46,166	43,335	42,315	41,853	42,390	40,823
[3] Drug-Related % of Adult Charges	35.1%	34.7%	34.3%	33.9%	33.8%	33.7%	34.5%	34.7%	32.1%	27.9%	28.7%	33.3%
[4] Total Adult Charges Related to Opioids	3,268	3,145	3,982	4,533	5,294	5,063	4,774	4,684	4,417	4,041	4,240	4,967
[5] Total Adult Charges Related to Drugs	20,277	19,476	18,674	17,873	18,157	16,979	15,912	15,023	13,585	11,680	12,161	13,579
[6] Opioid % of Drug-Related Adult Charges	16.1%	16.1%	21.3%	25.4%	29.2%	29.8%	30.0%	31.2%	32.5%	34.6%	34.9%	36.6%
Opioid-Related Percent of Criminal Activity -- Summit												
	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
<b>PANEL A - OPIOID-RELATED % OF CRIMES (Prosecutor / Court of Common Pleas / Sheriff / Adult Probation)</b>												
[1] Total Offenses Related to Drugs	1,160	544	743	847	756	895	851	715	842	942	962	911
[2] Total Offenses Reported	4,093	2,128	2,990	2,904	2,964	3,086	2,881	2,572	2,843	2,877	2,860	2,820
[3] Drug-Related % of Crimes	28.3%	25.6%	24.9%	29.2%	25.5%	29.0%	29.5%	27.8%	29.6%	32.8%	33.6%	32.3%
[4] Total Offenses Related to Opioids	221	107	196	233	235	278	273	238	284	330	338	333
[5] Total Offenses Related to Drugs	1,160	544	743	847	756	895	851	715	842	942	962	911
[6] Opioid % of Drug-Related Crimes	19.1%	19.7%	26.4%	27.5%	31.0%	31.0%	32.0%	33.2%	33.7%	35.0%	35.2%	36.6%
<b>PANEL B - OPIOID-RELATED % OF PRISONERS (Sheriff Jail / Alternative Corrections)</b>												
[1] Total Drug-Related State Prisoners	421,455	427,549	411,156	401,623	390,780	376,290	360,701	362,121	355,094	342,926		
[2] Total State Prisoners	1,311,540	1,335,642	1,341,699	1,341,454	1,336,979	1,317,105	1,290,580	1,299,900	1,288,600	1,272,900		
[3] Drug-Related % of Prisoners	32.1%	32.0%	30.6%	29.9%	29.2%	28.6%	27.9%	27.9%	27.6%	26.9%	26.9%	26.9%
[4] Total Opioid-Related State Prisoners	71,929	72,501	92,586	105,160	116,259	114,091	112,354	116,476	117,703	119,316		
[5] Total Drug-Related State Prisoners	421,455	427,549	411,156	401,623	390,780	376,290	360,701	362,121	355,094	342,926		
[6] Opioid % of Drug-Related Prisoners	17.1%	17.0%	22.5%	26.2%	29.8%	30.3%	31.1%	32.2%	33.1%	34.8%	34.8%	34.8%

Extrapolated using closest relevant data.

Extrapolated using national data.

Extrapolated based on one observation.

163. As a further extrapolation related to the blue category, Professor Cutler estimates the share of drug-related crimes associated with opioids using NSDUH survey data on the number of individuals with Substance Use Disorder (SUD) and Opioid Use Disorder (OUD) from 2006 to 2013. This methodology assumes that the percent of individuals with illicit SUD reporting an opioid use disorder is the same as the percent of criminals under the influence of drugs using opioids. Three key issues challenge the reliability of this assumption: (1) the share of

<sup>243</sup> See Cutler Report, at Appendix III.C1-2.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

ODU individuals and the share of criminals using opioids do not have the same denominators (e.g., illicit SUD individuals do not represent all drug users), (2) there is no evidence put forth that the probability of committing a crime due to opioid use equals the probability of having OUD if you have been diagnosed with SUD, and (3) estimates for 2014-2017 are entirely based on 2013 data.

$$\text{Equation 3: } \frac{\# \text{ individuals OUD}}{\# \text{ individuals SUD}} \rightarrow \% \text{ drug related crimes due to opioids}$$

164. Professor Cutler does not address the inconsistency between the populations of individuals with SUD and individuals engaging in criminal activity. The likelihood of committing a crime is associated with several socio-economic characteristics relevant to the population of inmates that differ from the broader category of individuals diagnosed with SUD.<sup>244</sup> Thus Professor Cutler's extrapolation of the percentage of individuals with SUD also diagnosed with OUD improperly confuses populations. Consequentially, this inappropriate extrapolation of population proportions might overestimate Professor Cutler's estimated share of criminal activity attributable to opioids.
165. Further, Professor Cutler's calculation of the share of drug-related crimes due to opioids assumes the likelihood of committing a crime (1) to obtain opioids, or (2) from the influence of opioid consumption equals the probability of having opioid use disorder (OUD) if you have a substance use disorder (SUD), as shown in Equation 3.
166. This assumption disregards the probability of committing a crime due to *non-opioid* drugs. Professor Cutler provides no evidence that opioid consumption *causes* one to engage in criminal activity at the same rate as individuals being diagnosed with OUD within the SUD population. Results from SILJ referenced above indicate non-opioid drugs most often induce criminal activity. As shown in Exhibit 37 below, of individuals who committed crimes under the influence of drugs, 13% were using heroin and only 2% were using other opioids.<sup>245</sup> Professor Cutler's extrapolated percentages of drug-related crimes are significantly higher

<sup>244</sup> See Caulkins, J. & Kleiman, M. "How Much Crime is Drug-Related? History, Limitations, and Potential Improvements of Estimation Methods." *National Criminal Reference Service* (Apr. 2014), available at <https://www.ncjrs.gov/pdffiles1/nij/grants/246404.pdf>

<sup>245</sup> See Bureau of Justice Statistics. Survey of Inmates In Local Jails (SILJ). Survey question S8Q9c (2002), available at <https://www.bjs.gov/index.cfm?ty=dcdetail&iid=274>.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

than the share of inmates reporting opioid use at the time of the offense according to SILJ, indicating a likely overestimate of harms.

**Exhibit 37: Percent of Inmates Under the Influence of Drugs**

	<b>Total Respondents</b>	<b>% of Respondents</b>	<b>% Yes</b>
<b>Total Inmates Surveyed</b>	<b>6,982</b>		
<i>"Were you under the influence of drugs at the time of the offense?"</i>			
Refused, Don't Know, or Blank	4,261	61%	
No	1,260	18%	
Yes	1,461	21%	
<i>"What drugs were you under the influence of? Any others?"</i>			
Marijuana	625	9%	43%
Crack	384	5%	26%
Methamphetamine (ice/crank)	245	4%	17%
Cocaine other than crack	244	3%	17%
Heroin	195	3%	13%
Tranquilizers such as valium	59	1%	4%
Barbiturates	37	1%	3%
Other opiates or methadone outside of treatment	32	0%	2%
Other amphetamine (speed) without a prescription	32	0%	2%
PCP	32	0%	2%
Ecstasy	27	0%	2%
LSD or other hallucinogens	26	0%	2%
Methaqualone (Quaaludes)	16	0%	1%
Other	69	1%	5%

**Source:** SILJ 2002; <https://www.icpsr.umich.edu/icpsrweb/ICPSR/studies/4359#> (at S8Q9b.-S8Q9c).

## 2. Estimation of the share of Children's and Family Services harms due to opioid lacks data and support

167. In another division relevant to his harms, Professor Cutler calculates the percentage of child removals related to opioids for twelve years using only one year of data.<sup>246</sup> Professor Cutler extrapolates 2015 child removals in which parents were opioid users to address missing data in the periods 2006-2014 and 2016-2017. He inadequately examines two key issues: (1) several external factors likely influence the annual volume of child removals, and (2) also missing is the share of child removals due to opioid abuse. To address this missing

<sup>246</sup> The percentage of child removals related to opioids is used to calculate harms for Children's and Family Services and Juvenile Court Activity. See Cutler Report at ¶¶ 44-45.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

information, he further extrapolates from unrelated data regarding addiction treatment services.

168. Professor Cutler does not account for factors affecting the number and nature of child removals in Cuyahoga and Summit County unrelated to opioids. For example, because socioeconomic status affects one's ability to care for children, factors such as poverty, employment, and healthcare coverage are associated with the volume of children without a proper home.<sup>247</sup>
169. Further, Professor Cutler does not address the Department of Children's and Family Services (DCFS) in Cuyahoga and Summit counties' ability to influence the number of child removals by (1) determining criteria for removing a child from parental control, and (2) attempting to improve child and family welfare.<sup>248</sup> For example, the National Coalition for Child Protection Reform (NCCPR) discusses the consequences of aggressive policy implementation by local child services departments. NCCPR's Issue Paper 13 focuses on child welfare and substance abuse, contending, "the foster care numbers are increasing not because of the drug abuse, but because of child welfare's typically stupid, knee-jerk take-the-child-and-run response to the drug abuse."<sup>249</sup> These factors are considerations for the mitigation of damages issue I explain in my evaluation of Professor McGuire's work.
170. Professor Cutler assumes a single result from a 2015 study on drug-related child removals in each county can be extrapolated to eleven other years only modified by the trend of services provided to address opioid addiction. Without support, the extrapolation assumes a relationship between addiction services (and related expenditures) and child removals and fails to consider the generality of the 2015 observation. Thus, Professor Cutler apparently is

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<sup>247</sup> See e.g., Dworsky, Amy. "Families At The Nexus Of Housing And Child Welfare," ChildWelfare.gov (Nov. 2014), available at <http://childwelfaresparc.org/wp-content/uploads/2014/12/Families-at-the-Nexus-of-Housing-and-Child-Welfare.pdf>. e.g., Martin, Megan and Citrin, Alexandra. "Prevent, Protect & Provide: How child welfare can better support low-income families", ChildWelfare.gov (Aug. 2014), available at <http://childwelfaresparc.org/wp-content/uploads/2014/08/Prevent-Protect-Provide-Brief.pdf>. See e.g., "Issue Paper 6: Child Abuse and Poverty." *National Coalition for Child Protection Reform* (Sep. 7, 2015), available at <https://nccpr.org/issue-papers-family-preservation-foster-care-and-reasonable-efforts/>

<sup>248</sup> "Issue Paper 2: Foster Care Panics." *National Coalition for Child Protection Reform* (Sep. 7, 2015), available at <https://nccpr.org/issue-papers-family-preservation-foster-care-and-reasonable-efforts/>

<sup>249</sup> "Issue Paper 13: Child Welfare and Substance Abuse." *National Coalition for Child Protection Reform* (Jul. 18, 2017), available at <https://nccpr.org/issue-papers-family-preservation-foster-care-and-reasonable-efforts/>

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

assuming that the pattern of addiction services over time is a reliable proxy for the pattern of drug-related child removals over time. If this is not the case, Professor Cutler's results will be biased.

171. As an example of the possible error that Professor Cutler is introducing through his methods, information for Summit's Children Services Annual Report of 2016 indicates that 12.5% of child removals were related to parental opiate use in 2016.<sup>250</sup> Professor Cutler's extrapolation of the 2015 observation, however, yields [REDACTED] opioid-related removals in 2016, thus indicating a potentially substantial error in his estimates.
172. In addition, Professor Cutler uses a portion of the extrapolated 2015 shares of child removals with parental opioid use to a completely different harm category--Juvenile Court Activity. Professor Cutler relies on his estimated shares of opioid-related child removals for 2006-2017 to calculate the percent of 'Abuse, Dependency, Neglect' cases in juvenile court attributable to opioids without further analysis of the error introduced by such extrapolation across categories.

**E. Professor Cutler does not adequately consider the role of the public sector in the measurement and cause of harms and related expenditures**

173. Professor Cutler's analysis does not provide a reliable way of allocating responsibility for harms between Defendants, Non-Defendants, and third-party organizations in the public sector.
174. In his report, Professor Cutler refers to the harms he calculates for each division as "indivisible harms" and states that "it is unlikely that a unique attribution of harm to each contributing party is possible."<sup>251</sup> Professor Cutler defines an "indivisible harm" as a harm where multiple "parties are responsible for the full extent of the harm" and where multiple parties had to fail their responsibilities in order for the harm to occur.<sup>252</sup>

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<sup>250</sup> This percentage was calculated based on the following statement: "In fact, half of the children who entered foster care in 2016 came from families where at least one parent struggled with substance abuse. And, one in four of these children came from homes where an opiate was the primary substance." See Summit County Children Services, "2016 Annual Report: The Challenge of Protecting Children During the Opioid Epidemic," (2016) at p. 2.

<sup>251</sup> See Cutler Report, at ¶ 31.

<sup>252</sup> See Cutler Deposition Vol. 1, 71:15-72:4.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

175. Professor Cutler’s framework “does not rely upon any specific delineation as to who it was that caused the harm” and therefore captures the shared responsibility for all entities including Plaintiffs, Defendants, and non-Defendants.<sup>253</sup> In his deposition Professor Cutler maintains that he has not made any determination as to which parties are at fault for these harms and that “one could not assign a percentage of the blame to each party”.<sup>254</sup>
176. Public sector organizations are substantially involved in the supply chain for opioid products including but not limited to agencies such as FDA, DEA, United States Postal Service (“USPS”), and PDMPs. Below I explain why Professor Cutler must address the roles of these organizations in estimating his proportions of harms relevant to the work of Professor McGuire.

**1. Professor Cutler does not consider the role of DEA**

177. The DEA is responsible for providing oversight over the manufacturing, distribution and prescribing of controlled substances in the United States.<sup>255</sup> The organization is tasked with administering and enforcing the Controlled Substances Act (“CSA”) and, in conjunction with the Attorney General, has both the ability and responsibility to deny, revoke or suspend the registration of any party that violates the CSA.<sup>256</sup> A failure of Professor Cutler’s framework, which he essentially admits, is that it cannot isolate the impact of the DEA on harms.<sup>257</sup>
178. For example, the bipartisan House Energy and Commerce Committee (“The Committee”) investigated the role of the DEA in the monitoring and enforcement of opioid distribution in West Virginia.<sup>258</sup> The Committee’s investigation “identified weaknesses in the DEA’s enforcement posture in West Virginia as well as policy approaches that appear to have limited the agency’s ability to take enforcement action against registrants suspected of

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<sup>253</sup> See Cutler Deposition Vol. 1, 73:7-73:14.

<sup>254</sup> See Cutler Deposition Vol. 1, 71:15-74:2.

<sup>255</sup> See United States Department of Justice, “FY 2019 Budget and Performance Summary – Drug Enforcement Administration (DEA),” (Mar. 15, 2018), *available at* <https://www.justice.gov/jmd/page/file/1033151/download>.

<sup>256</sup> See United States House of Representatives Energy and Commerce Committee. “Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia,” (Dec. 19, 2018) (“West Virginia Report”) pp. 26-28.

<sup>257</sup> See Cutler Deposition Vol. 1, 97:8-97:14.

<sup>258</sup> See West Virginia Report, p. 25.



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

diversion.”<sup>259</sup> This investigation also addressed the DEA’s role in preventing opioid-related harms across the county. The findings derived from the Committee’s report question “the efforts of the DEA, to prevent diversion in other areas of the country that have been impacted by the opioid epidemic”.<sup>260</sup>

179. As noted, the DEA has a means for recording and tracking controlled substances transactions known as the Automation of Reports and Consolidated Orders System (“ARCOS”). ARCOS “allows the agency to track controlled substances from the time they are manufactured until they are dispensed to consumers through pharmacies, doctors or other means.”<sup>261</sup>
180. Importantly, The Committee found that “the DEA did not utilize these data in a proactive manner to combat controlled substance diversion.”<sup>262</sup> The Committee’s conclusion in West Virginia was that “had the DEA better used ARCOS data to identify potentially problematic pharmacies, it could have better leveraged its resources to combat diversion.”<sup>263</sup> The report finds that the DEA failed to adequately use its enforcement tools to prevent diversion.<sup>264</sup>
181. Both Professor Gruber and Professor Cutler acknowledge the role the DEA played in the market contractions post-2010 that led to the increase in harms from illicit opioids.<sup>265</sup> However, Professor Cutler attributes no portion of the harms he estimated to the DEA even though they apparently had an instrumental role in preventing diversion in the Track 1 Jurisdictions.<sup>266</sup>

**2. Professor Cutler does not consider the role of public insurance**

182. Another important factor in the expansion of opioid-related harms that Professor Cutler does not consider is the role of public insurance. Again Professor Cutler does not attempt to make a determination as to which parties are at fault for increased shipments or resulting harms and does not discuss the role that public insurance played in determining who received

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<sup>259</sup> See West Virginia Report, p. 45.

<sup>260</sup> See West Virginia Report, p. 44.

<sup>261</sup> See West Virginia Report, p. 53.

<sup>262</sup> See West Virginia Report, pp. 52-53.

<sup>263</sup> See West Virginia Report, p. 57.

<sup>264</sup> See West Virginia Report, pp. 318 and 322.

<sup>265</sup> See Gruber Report ¶46. See also Cutler Report ¶¶51 and 52. See also Cutler Deposition Vol. 1, 98:16-100:8.

<sup>266</sup> See Cutler Deposition Vol. 1, 98:16-101:21.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

opioids both legally and illegally.<sup>267</sup> While Professor Cutler includes age as an explanatory variable in his models, he does not acknowledge the evolution in Medicare coverage over the past two decades and therefore ignores that role that changing Federal law played in expanding access to opioids.

183. The Council of Economic Advisers (“CEA”) prepared a report on “The Role of Opioid Prices in the Evolving Opioid Crisis” that discusses the role of expanding government health care coverage on the price of opioids.<sup>268</sup> The CEA report finds that “The falling prices were a consequence of the expansion of government health care coverage, which increased access to all prescription drugs—including opioids” and that “these falling out-of-pocket prices effectively reduced the price of opioid use not only in the primary market but also in the secondary (black) market for diverted opioids”.<sup>269</sup>
184. The analysis by the CEA finds that “the share of prescription opioids provided for beneficiaries in government programs grew from 17 percent to 60 percent of all opioid prescriptions and accounted for three-fourths of the growth in prescription opioids between 2001 and 2010.”<sup>270</sup> Professor Cutler does not attempt to account for this substantial shock to the opioid market in his analysis, nor does he attempt to discuss the role the Federal government had in monitoring its beneficiaries to limit diversion.<sup>271</sup>
185. The CEA acknowledges the role the government played in subsidizing the purchase of prescription opioids as well as the roles of specific public programs.<sup>272</sup> The primary drivers are the introduction of Medicare Part D and the increase in Social Security Disability

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<sup>267</sup> See Cutler Deposition Vol. 1, 71:15-74:2.

<sup>268</sup> See White House Council of Economic Advisers. “The Role of Opioid Prices in the Evolving Opioid Crisis,” (Apr. 2019).

<sup>269</sup> See White House Council of Economic Advisers. “The Role of Opioid Prices in the Evolving Opioid Crisis,” (Apr. 2019), p. 1.

<sup>270</sup> See White House Council of Economic Advisers. “The Role of Opioid Prices in the Evolving Opioid Crisis,” (Apr. 2019), p. 2.

<sup>271</sup> In the early 2010s, Medicare substantially reduced the reimbursement for Urine Drug Testing, a method physicians used to ensure that patients consumed their prescribed opioids that also would have acted as a diversion deterrent. See e.g., Dowell, Haegerich, and Chou. “CDC Guideline For Prescribing Opioids For Chronic Pain — United States, 2016.” MMWR. Recommendations and Reports 65.1 (2016): 1-49, (March 15, 2016). See e.g., “Liquid Gold: Pain Doctors Soak Up Profits By Screening Urine For Drugs”, *Modern Healthcare*, (Nov. 7, 2017), available at <https://www.modernhealthcare.com/article/20171107/NEWS/171109896/liquid-gold-pain-doctors-soak-up-profits-by-screening-urine-for-drugs>.

<sup>272</sup> See White House Council of Economic Advisers. “The Role of Opioid Prices in the Evolving Opioid Crisis,” (Apr. 2019), p. 6.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

Insurance (“SSDI”). This report states that “any role of SSDI expansion in the opioid crisis would be attributable to the design of the program” and “likely was a result of insufficient protections against the nonmedical use of prescription opioids”.<sup>273</sup>

186. Previous research has studied the role and impact that public funding for opioids had on harms. For example, the CEA acknowledges “that a Medicare Part D–driven 10 percent increase in opioid prescriptions results in 7.4 percent more opioid-involved overdose deaths among the Medicare-ineligible population.”<sup>274</sup> Importantly, Professor has not isolated the effects of these programs on opioid-related mortalities and therefore might overestimate the harms due to the Alleged Conduct.

**3. Professor Cutler does not consider the role of other organizations**

187. In addition to the organizations discussed above, Professor Cutler fails to account for the role of several other public sector entities in mitigating opioid-related harms. I have included a handful of examples below supported by recent investigations, but I do not attempt to provide an exhaustive list. Instead, I provide certain examples that Professor Cutler should have considered when attributing harms to the Alleged Conduct.
188. The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of drugs in the United States.<sup>275</sup> The FDA approves every opioid product manufactured and prescribed in the U.S. and is responsible for helping the public get the accurate, science-based information they need to use medical products to improve their health.<sup>276</sup> Importantly, FDA is charged with approving certain information regarding the indicated use of opioid products.<sup>277</sup> FDA Commissioner Scott Gottlieb acknowledged that the scope of opioid harms are the result of “many past mistakes and many

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<sup>273</sup> See White House Council of Economic Advisers. “The Role of Opioid Prices in the Evolving Opioid Crisis,” (Apr. 2019), pp. 6-7.

<sup>274</sup> See White House Council of Economic Advisers. “The Role of Opioid Prices in the Evolving Opioid Crisis,” (Apr. 2019), pp. 27. See also Powell, David, Rosalie Liccardo Pacula, and Erin Audrey Taylor. “How Increasing Medical Access to Opioids Contributes to the Opioid Epidemic: Evidence from Medicare Part D.” Santa Monica, CA: RAND Corporation, (2016).

<sup>275</sup> See United States Food and Drug Administration. “What We Do,” available at <https://www.fda.gov/about-fda/what-we-do>.

<sup>276</sup> See United States Food and Drug Administration. “What We Do,” available at <https://www.fda.gov/about-fda/what-we-do>.

<sup>277</sup> See Rosenthal Report ¶¶18-22. See, e.g., 21 C.F.R. §202.1.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

parties who missed opportunities to stem the crisis, including the FDA.”<sup>278</sup> Professor Cutler does not isolate any actions by the FDA affecting harms in the Track 1 Jurisdictions.<sup>279</sup>

189. Recent evidence indicates that the United States Postal Service may play a large role in the distribution of illicit opioids.<sup>280</sup> The United States Senate Permanent Subcommittee on Investigations released a report in 2018 that discussed combatting the illicit opioids entering the country through the mail.<sup>281</sup> Investigators for the Senate Homeland Security subcommittee have found that the agency is “unequipped to check for illegal substances being shipped”.<sup>282</sup>
190. The role of the public sector is not limited to the federal government. The State of Ohio Board of Pharmacy plays an important role in the regulation of the prescription opioid market in Ohio. The Ohio Board of Pharmacy interacts with (1) regulatory and administrative changes to rules and laws, (2) proactive inspections at licensed locations, (3) prevention education, and (4) the OARRS program.<sup>283</sup> A significant change to the prescribing environment in Ohio occurred when the State of Ohio Board of Pharmacy created Ohio’s Prescription Drug Monitoring Program (“PDMP”) in 2006.<sup>284</sup>
191. The Ohio PDMP is known as the Ohio Automated Rx Reporting System (“OARRS”) and it collects information on all outpatient prescriptions for controlled substances.<sup>285</sup> OARRS is a tool that can be used by professional licensing boards and law enforcement to address prescription drug diversion and abuse.<sup>286</sup> In particular, the State of Ohio Board of Pharmacy

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<sup>278</sup> See FDA. “Statement from FDA Commissioner Scott Gottlieb, M.D. on the agency’s 2019 policy and regulatory agenda for continued action to forcefully address the tragic epidemic of opioid abuse,” *available at* <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-2019-policy-and-regulatory-agenda-continued>.

<sup>279</sup> See Cutler Deposition Vol. 1, 97:16-97:21.

<sup>280</sup> See Jr., Tom Howell. “U.S. Postal Service Unwittingly Smuggles Chinese Opioids to American Addicts.” *The Washington Times* (Jan. 24, 2018), *available at* <https://www.washingtontimes.com/news/2018/dec/4/us-postal-service-will-suspend-most-delivery-and-r/>.

<sup>281</sup> See Committee on Homeland Security and Governmental Affairs Report, “Combatting the Opioid Crisis: Exploiting Vulnerabilities in International Mail,” (Jan. 23, 2018).

<sup>282</sup> See Morris, Chris. “How the U.S. Postal Service Became Entangled in the Opioid Epidemic,” *Fortune* (Jan. 25, 2018), *available at* <http://fortune.com/2018/01/25/opioid-epidemic-china-us-postal-service/>.

<sup>283</sup> See Griffin Deposition, 70:20-72:13.

<sup>284</sup> See Griffin Deposition, 72:12-72:24.

<sup>285</sup> See Griffin Deposition, 77:22-77:25.

<sup>286</sup> See Ohio Board of Pharmacy. “About: What is OARRS.” *available at* <https://www.ohiopmp.gov/About.aspx>.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

uses the OARRS tool to analyze prescribing information and identify “prescribers that write prescriptions for non-legitimate medical used” or “drug trafficking”.<sup>287</sup>

192. Professor Cutler did not conduct any research into the development of Ohio’s prescription drug monitoring program.<sup>288</sup> There is no mention of the role of OARRS in Professor Cutler’s report, nor can he identify the name of the PDMP during his deposition.<sup>289</sup> Although Professor Cutler acknowledges the role that the public sector played in exacerbating the opioid-related harms in the Track 1 Jurisdictions, his methodology fails to control for the impact and likely overestimates the impact from the Alleged Conduct.

**F. Professor Cutler does not appropriately examine the causality of diversion misconduct**

193. Professor Cutler’s model is incapable of calculating mutually exclusive harms due to marketing misconduct and diversion misconduct. Rather, Professor Cutler presents harms attributable to distributor misconduct based on inputting alternative numbers into his model, with no attempt to (1) validate these inputs, or (2) determine whether his model is or is not appropriate to estimate harms related to diversion.<sup>290</sup>
194. Professor Cutler does not address the causality of diversion misconduct but, instead, essentially acts as a calculator using information from Counsel without any independent analysis. The model presented by Professor Cutler does not change based on the alleged *source* of excess shipments and, therefore, cannot adequately measure the impact of Defendants’ misconduct on harm. Professor Cutler notes that his model “takes as an input estimates of the harms that result from misconduct of particular parties...and then it estimates the harms that result from that. But by itself the model does not consider any specific party.”<sup>291</sup> Professor Cutler presents a model that is insensitive to the *type* of misconduct associated with the alleged harm and, therefore, cannot properly examine causality within his economic framework. As a consequence of the model’s lack of differentiation among the distinct aspects of the Alleged Conduct across Defendants,

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<sup>287</sup> See Griffin Deposition, 80:25-81:20.

<sup>288</sup> See Cutler Deposition Vol. 2, 653:3-653:8.

<sup>289</sup> See Cutler Deposition Vol. 2, 653:9-653:22.

<sup>290</sup> See Cutler Deposition Vol. 2, 594:11-599:18.

<sup>291</sup> See Cutler Deposition Vol. 2, 89:10-91:11.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

Professor Cutler’s analysis of diversion activity only pertains to distributor misconduct, not manufacturer misconduct.<sup>292</sup>

**G. Professor Cutler’s inadequate consideration of uncertainty in his indirect approach undermines his opinions on but-for harms**

**1. The indirect model assumes the relationship in the baseline holds for every year thereafter and disregards the impacts of later events on mortality**

195. Professor Cutler’s indirect framework (i.e. “residual” model) estimates predictors of opioid-related mortality entirely based on one period in time. In the case of the indirect model for illicit mortality under Approach 1, mortality rates are predicted for 2011-2016 using 2008-2010 county-specific observations. Under Approach 2, the base period is 1993 to 1995, requiring a much longer period during which the estimated relationship is assumed to be a good description of the true economic relationships.
196. Importantly, as Professor Cutler acknowledges, the indirect approach essentially memorializes relationships in the base period to make future projections.<sup>293</sup> The selection of the base period is critical to ensuring the model’s reliability for future projections. For example, if counties experienced high unemployment rates in the 2008-2010 base period and *also* had elevated mortality rates in the period, then subsequent decreases in unemployment after 2010 will predict a decrease in mortality even if reality indicates otherwise. When the methodology is applied in Approach 2, the relationship between unemployment and mortality in the early 1990s is assumed to remain valid two decades later. It is widely recognized that an economic model’s reliability to project relationships decreases substantially the further away the projection is from the base period even if carefully selected.<sup>294</sup>

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<sup>292</sup> Professor Cutler’s results in Appendix III.J “[yield] an estimate of the harms attributable to distributors’ misconduct” and “[t]he estimates of the share of harms due to defendants’ misconduct for Cuyahoga and Summit Counties reported in Tables III.16A-B do not attempt to uniquely attribute harm resulting from actions by any individual type of defendant.” See Cutler Report, Appendix III.J, at ¶¶ 3 and 6.

<sup>293</sup> See Cutler Report at fn 53, p. 45.

<sup>294</sup> See, e.g., Pindyck, Robert S. and Daniel L. Rubinfeld. (1997). *Econometric Models and Economic Forecasts*. 4th ed. Boston, MA: McGraw-Hill/Irwin; Chapter 16.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**2. Omitted factors increase the error of Professor Cutler’s models**

197. In addition to the error inherent in long-term projections, Professor Cutler’s indirect model does not adequately capture the influences on mortality rates in the baseline period and likely overstates the impact of shipments on harm.<sup>295</sup> The analysis does not account for variables associated with changes in drug use and/or mortality, such as homeless population, suicide rate, religion, and marriage rates.<sup>296</sup> As previously discussed in Section IV.D.5, research discusses the measures of “despair” in the U.S. as key influences in the growth of mortality overall.<sup>297</sup> Exhibit 38 lists a number of factors omitted from Professor Cutler’s modeling that likely explain some portion of changing mortality rates since the early 1990s.

**Exhibit 38: Omitted Variables from Professor Cutler’s Analysis<sup>298</sup>**

<b>Variable</b>	<b>Economic Theory</b>
Changing religious practices	<i>See</i> Case & Deaton (2017)
Eligibility for Medicare Part D	<i>See</i> CEA Report
Eligibility for disability insurance	<i>See</i> CEA Report
Exposure to trade liberalization	<i>See</i> Case & Deaton (2017)
Geographic location	<i>See</i> Case & Deaton (2017)
Incidence of cancer	<i>See</i> Case & Deaton (2017)
Marriage rates	<i>See</i> Case & Deaton (2017)
Number of out of wedlock births	<i>See</i> Case & Deaton (2017)
Parents living apart from children	<i>See</i> Case & Deaton (2017)
Percentage of population insured	<i>See</i> Rosenthal Report
Prevalence of mental health disorders	<i>See</i> Case & Deaton (2017)
Suicide rate	<i>See</i> Case & Deaton (2017)

198. Although Professor Cutler admits “[o]ne absolutely needs to consider despair in looking at mortality patterns,” he fails to acknowledge the unobserved effect of despair in his model.<sup>299</sup> He reasoning for omitting factors to capture “cultural despair” is based on data limitations.

<sup>295</sup> *See* Cutler Deposition Vol 2., 553:15 – 556:21.

<sup>296</sup> *See* Cutler Deposition Vol. 2, 469:6-471:15.

<sup>297</sup> *See* Section IV.D.5. *See also* Case and Deaton (2017).

<sup>298</sup> These omitted variables apply to Professor Cutler’s direct and indirect models.

<sup>299</sup> *See* Cutler Deposition Vol. 2, 478:24-482:1.



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

There is, however, information on factors such as suicide rates that could have been used in Professor Cutler's model which he apparently ignored.

**3. As time passes, Professor Cutler's model is less reliable and blurs the difference between actual and predicted values**

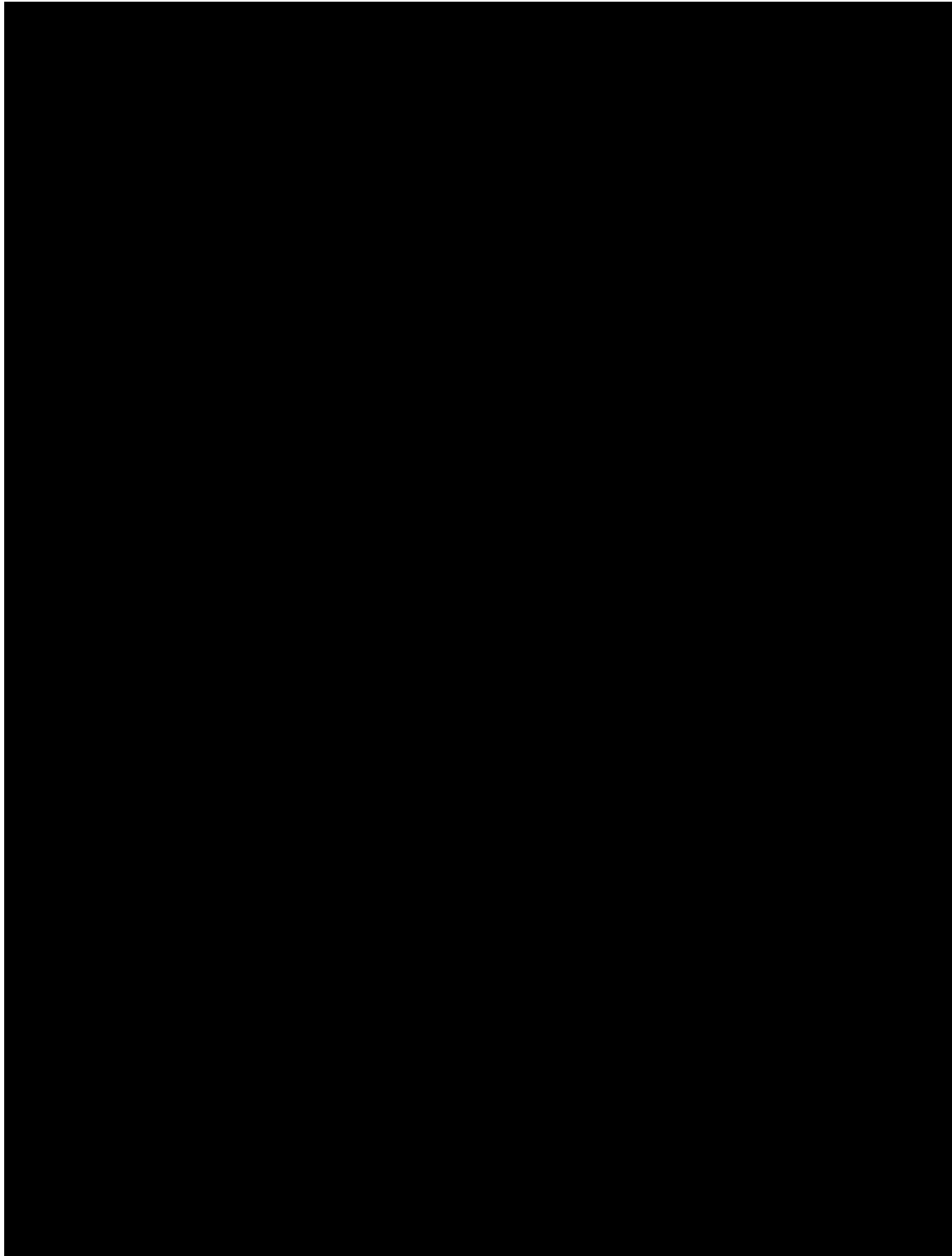
199. Professor Cutler's indirect model does not consider uncertainty over time. One can expect the error estimated in a model to increase as the predicted values move farther away from the sample, i.e. as time increases. However, Professor Cutler's utilization of a residual model does not adjust for the effect of time on the reliability of his estimates. As discussed above, both Professors Rosenthal and Cutler acknowledged the uncertainty of out-of-period predictions in their depositions.<sup>300</sup>
200. Similar to the analysis shown for Professor Rosenthal's indirect model, Exhibit 39 and Exhibit 40 apply the same standard formulae to quantify the uncertainty in Professor Cutler's predicted values of all opioid mortality rates and illicit opioid mortality rates. The widening interval illustrates the growing uncertainty surrounding his results that compounds with every passing year. Importantly, this assessment of the potential prediction error demonstrates that Professor Cutler cannot rule out that the actual mortality rates differ from the but-for rates. Therefore, Professor Cutler's estimates are unreliable and become less reliable further from the baseline.

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<sup>300</sup> See Rosenthal Deposition Vol. 2, 509:3-509:9; Cutler Deposition Vol. 2, 545:14-546:1.

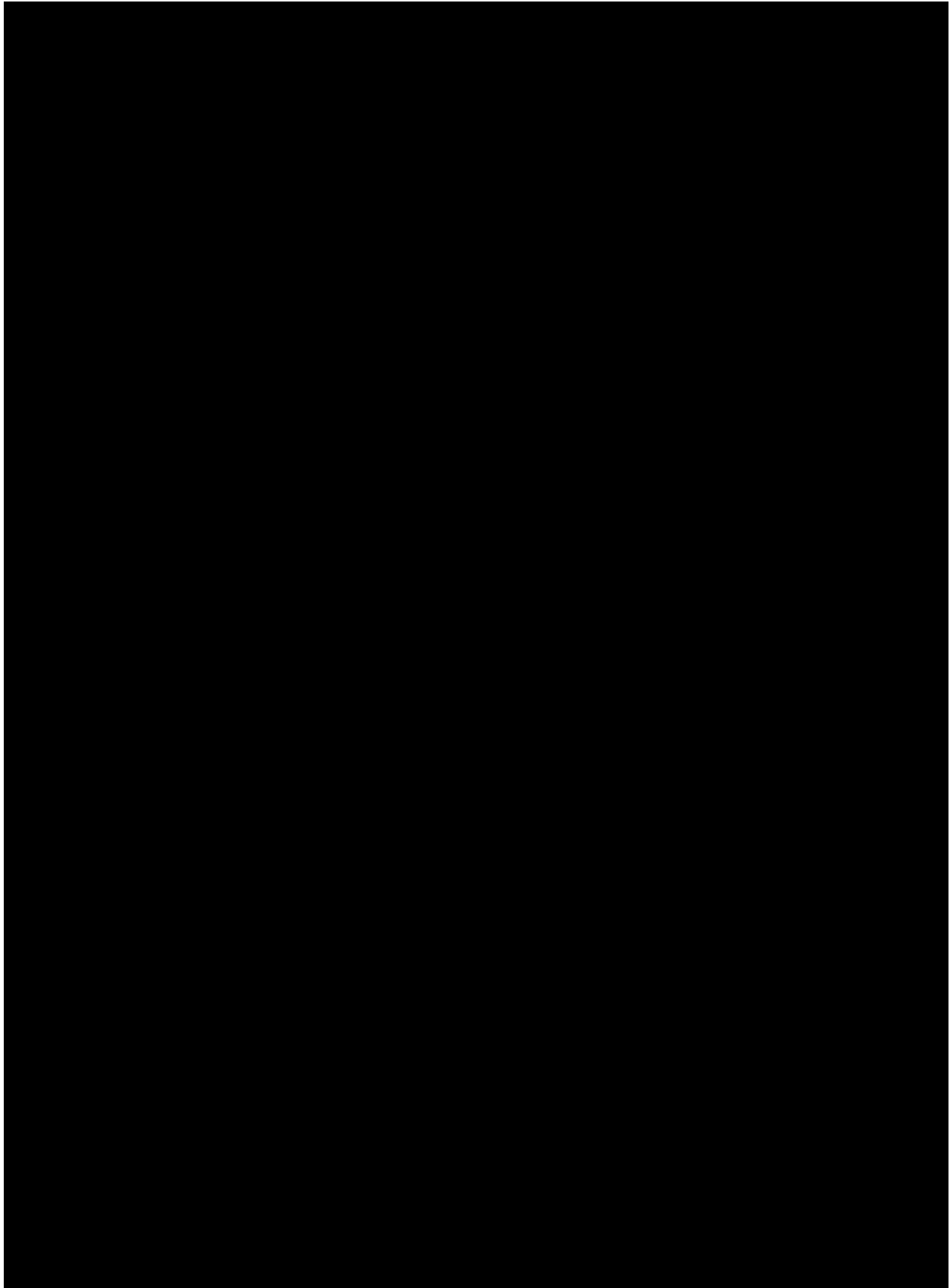
HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 39: Prediction Intervals for Predicted Illicit Mortality Under Professor Cutler's Approach 1**



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 40: Prediction Intervals for Predicted Any Opioid Mortality Under Professor Cutler's**



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**VI. Expert Report of Professor McGuire**

201. In the last stage of Plaintiffs' Economic Framework for estimating damages, Professor McGuire determines the divisions within the Bellwether governments that face costs he believes are related to Defendants' Alleged Conduct and attempts to quantify these affected costs by division for each year 2006 through 2018.
202. Professor McGuire's analysis does not meet the standards expected of an expert testifying to economic damages for at least six reasons. First, the calculation of damages relies entirely on the results of Professor Rosenthal's and Professor Cutler's flawed methodologies. Second, Professor McGuire fails to establish the existence of opportunity costs upon which his methodology relies. Third, the process by which Professor McGuire identifies affected divisions and determines affected costs within those divisions is not reproducible and is therefore unscientific and unreliable. Fourth, Professor McGuire does not consider the role of the public sector in his measurement of harms and related expenditures. Fifth, Professor McGuire does not consider the Plaintiffs' burden to mitigate the damages and therefore cannot reliably identify the actual amount of damages that were unavoidable in this case. Last, Professor McGuire is unable to apportion damages between licit and illicit opioids, between marketing and diversion allegations, or between individual Defendants.
203. In Sections A through F below, I address each of the specific reliability objectives that Professor McGuire fails to meet. I also explain why the deficiencies in his analysis imply that his damages calculations are not reliable within a reasonable degree of professional certainty.

**A. Professor McGuire's damages analysis relies on the reports of Professors Rosenthal and Cutler without validation**

204. As I have shown above, neither of the analyses of Professors Rosenthal and Cutler establish causation within a reasonable degree of professional certainty, and therefore the damages Professor McGuire calculates cannot be reliably attributed to the Alleged Conduct.
205. Professor McGuire does not attempt to provide his own causal link between the Alleged Conduct and the expenditures of Plaintiff counties in this matter. In his report and deposition, Professor McGuire repeatedly states that he relies upon the analyses of Professor Rosenthal and Professor Cutler before him to establish a causal link between Defendants' actions and

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

harms that the Bellwethers experience.<sup>301</sup> Guidance on proper damage methodology cautions against relying on another expert for causation.<sup>302</sup>

206. Professor McGuire bases his damages on the erroneous assumptions made earlier in the Economic Framework and does not attempt to verify, scrutinize, or in any way validate the results he uses in his calculations.
207. As I discuss in earlier in this report, the uncertainty introduced in Professor Rosenthal's model flows through to the damages calculated by Professor McGuire. In his deposition, Professor McGuire confesses that his analysis depends on any assumptions that feed into the conclusions of Professor Rosenthal.<sup>303</sup> This includes all of the uncertainty I describe earlier in this report. Importantly, the damages number presented in Professor McGuire's report relies on the unreasonable assumption that "virtually all promotion by the manufacturer Defendants from 1995 to the present was unlawful."<sup>304</sup> As I describe above, Professor Rosenthal employs convenient statistical devices and an improper series for the but-for stock of promotion to reach her conclusions and does not attempt to account for the uncertainty in her models. The final calculation of damages to the Bellwethers compounds all of these known weaknesses. Professor McGuire inadequately addresses the cascading uncertainty in the Economic Framework and as a result, his calculations are little more than pure speculation.
208. Professor Cutler provides Professor McGuire with all of the percentages that he applies to calculate damages from the total affected costs of each division.<sup>305</sup> In his deposition, Professor McGuire admits that he "did not conduct [his] own regression analysis," that he "didn't conduct any statistical tests" on Professor Cutler's results, nor did he replicate Professor Cutler's statistics.<sup>306</sup> Professor McGuire accepts all of the percentages based on Professor Cutler's work without modifying them in any way to account for any differences

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<sup>301</sup> See Deposition of Thomas McGuire, Ph.D., Vol. 1, *In Re National Prescription Opiate Litigation* (Apr. 23, 2019) ("McGuire Deposition Vol. 1"), at 203:1-207:8.

<sup>302</sup> See *Litigation Services Handbook*, at Section 4.4, p. 18.

<sup>303</sup> See McGuire Deposition Vol. 1, 363:19-366:2.

<sup>304</sup> See McGuire Deposition Vol. 1, 365:10-365:17.

<sup>305</sup> See McGuire Deposition Vol. 1, 147:5-147:8.

<sup>306</sup> See McGuire Deposition Vol. 1, 140:23-142:24.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

specific to the Bellwether counties.<sup>307</sup> Professor McGuire did not do any comparison between the “the data specific to Cuyahoga County or Summit County versus the data for these several hundred large counties that were part of Professor Cutler's analysis.”<sup>308</sup> Professor McGuire acknowledges that his report was not “empirical at that level” and that he “didn’t do it.”<sup>309</sup> Professor McGuire simply accepts both the causation and estimates as given and did not validate the results on which he relies.

209. In his deposition, Professor Cutler specifies that his percentages of harm should not simply be applied to an aggregate total dollar amount if the costs to address harms involving opioids are different from the costs to address harms not involving opioids.<sup>310</sup> Professor Cutler gives an example of this during his deposition by explaining that “if there were different costs for an autopsy for different reasons, that’s something that Professor McGuire would need to take into account.”<sup>311</sup> In any division where the cost to address an opioid-related harm (e.g. overdose autopsy, drug possession trial) is not the same as the cost to address a non-opioid-related harm (e.g. a drowning autopsy, a murder trial), Professor Cutler confirms that Professor McGuire “would require a different input than just, for example, the percentage of that activity which is due to opioids.”<sup>312</sup> But Professor McGuire accepts all of the percentages based on Professor Cutler’s work without modifying them in any way to account for any differences in costs the way Professor Cutler describes.<sup>313</sup>
210. Professor McGuire fails to provide any evidence that the opioid-related harms due to the Alleged Conduct (as provided by Professor Cutler) reliably equate to the proportion of expenditures by the county divisions. As I discuss in Section V.A.1, Professor Cutler assumes that mortality is a reliable proxy for the impact on harms specific to each division. Professor McGuire takes this assumption one step further and applies that estimate to all of the affected costs in a division equally. By applying a uniform percentage, Professor

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<sup>307</sup> See McGuire Deposition Vol. 1, 384:14-385:21. In particular, Professor McGuire accepts Professor Cutler’s national mortality impacts as equivalent to the impact on division expenditures without further review.

<sup>308</sup> See McGuire Deposition Vol. 1, 148:17-150:10.

<sup>309</sup> See McGuire Deposition Vol. 1, 148:17-150:10.

<sup>310</sup> See Deposition of David Cutler, Ph.D., Vol.1, *In Re National Prescription Opiate Litigation* (Apr. 26, 2019) (“Cutler Deposition Vol. 1”), 193:23-194:10.

<sup>311</sup> See Cutler Deposition Vol. 1, 193:5-194:12.

<sup>312</sup> See Cutler Deposition Vol. 1, 193:23-194:10.

<sup>313</sup> See McGuire Deposition Vol. 1, 384:14-385:21.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

McGuire assumes that both the costs of food supplies and the cost of court transcribing interpreters for Cuyahoga Juvenile Court would increase equally based on opioid-related mortality.<sup>314</sup> As a result of this over-simplification, Professor McGuire's damages calculation are not grounded in a reliable foundation.

**B. Professor McGuire's damages methodology is based on the existence of unproven opportunity costs**

211. Instead of quantifying excess costs, Professor McGuire employs an opportunity cost theory to identify activities that have been crowded out by the county's attention to services related to harms purportedly due to the Alleged Conduct.<sup>315</sup>
212. In his report Professor McGuire explains that "[a] fundamental principal of economics is that the cost of a resource is its value in its next best alternative."<sup>316</sup> The concept of opportunity cost requires establishing that expenditures could have been spent on these alternatives that are just as valuable. In his deposition however, Professor McGuire does not identify the alternatives for each division and states that he doesn't "need to know what exactly was done less" in order to apply his opportunity cost analysis.<sup>317</sup> Further, the opportunity cost framework as applied by Professor McGuire is used to calculate damages during a period where declining costs in some divisions confound his ability to directly observe the incremental costs due to the Alleged Conduct.
213. The costs for several of the divisions that Professor McGuire identifies are actually declining throughout the damages period. The division with the largest affected costs from 2006-2018 according to Professor McGuire is the Cuyahoga County Department of Child and Family Services ("Cuyahoga DCFS"). Total affected costs from Cuyahoga DCFS over this time period exceed 1.4 billion dollars. However, from 2006 to 2018 the annual costs are actually trending down.<sup>318</sup>

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<sup>314</sup> See McGuire Damages Report, at Appendix IV.C-6.

<sup>315</sup> See McGuire Damages Report, at ¶¶ 25-28.

<sup>316</sup> See McGuire Damages Report, at ¶ 27.

<sup>317</sup> See McGuire Deposition Vol. 1, 277:13-278:20.

<sup>318</sup> See McGuire Damages Report, Table IV.7.



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

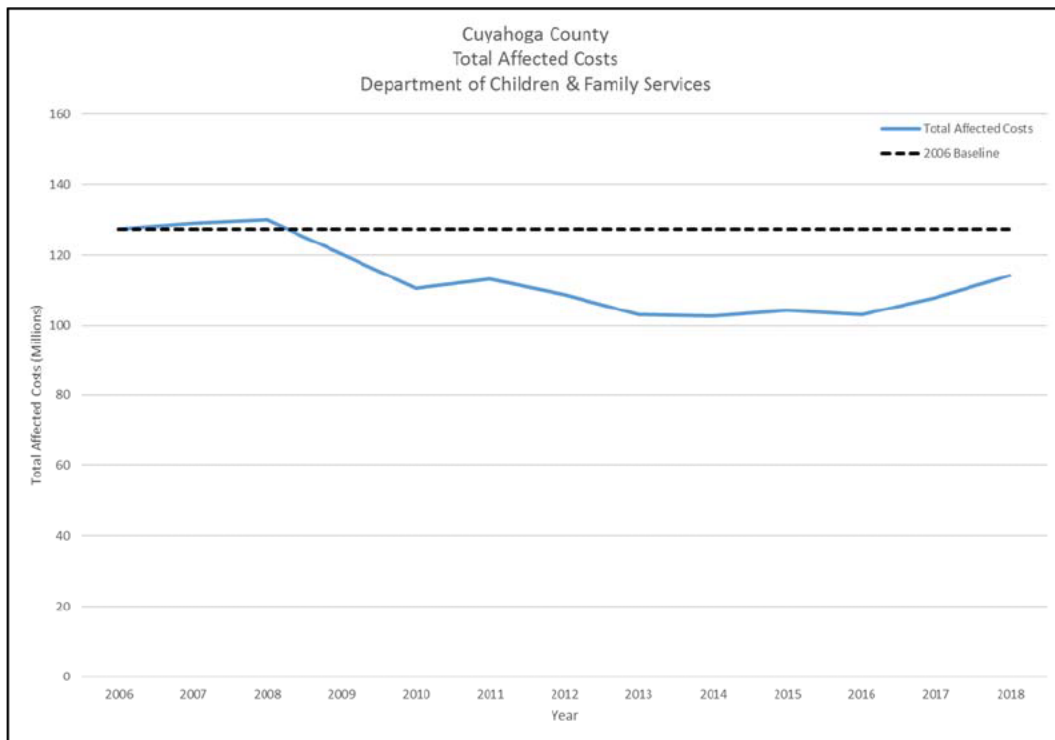
214. As Exhibit 41 below illustrates, the county expenditures that Professor McGuire believes could have been affected by opioids in this division were decreasing from 2006 levels. The first year of expenditure data includes \$127.5 million in affected costs and by 2016, this number fell to \$103.2 million. This evidence confounds the Plaintiffs’ claim that they have “incurred expenditures for special programs over and above Plaintiffs’ ordinary public services.”<sup>319</sup>
215. To support his identified divisions, Professor McGuire cites to news articles rather than empirical evidence. In December 2017 the *Akron Beacon Journal* reported that a, “tsunami of opioid affected children is flooding Ohio’s children services agencies, exploding county budgets and overwhelming available foster care resources.”<sup>320</sup> Professor McGuire does not provide any empirical analysis to support that the budgets of either of these divisions are “exploding” and does not cite to any study performed by or cited by the journal. In fact, the budget for Cuyahoga’s DCFS has *decreased* by approximately 10% between 2006 and 2018 and experienced on average a 1% decline each year.

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<sup>319</sup> See Cuyahoga Complaint at ¶ 1134; See Summit Complaint at ¶ 1105.

<sup>320</sup> See McGuire Damages Report, at ¶ 43.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 41: Cuyahoga County Department of Child and Family Services Affected Costs**

**Source:** McGuire Damages Report, Table IV.7.

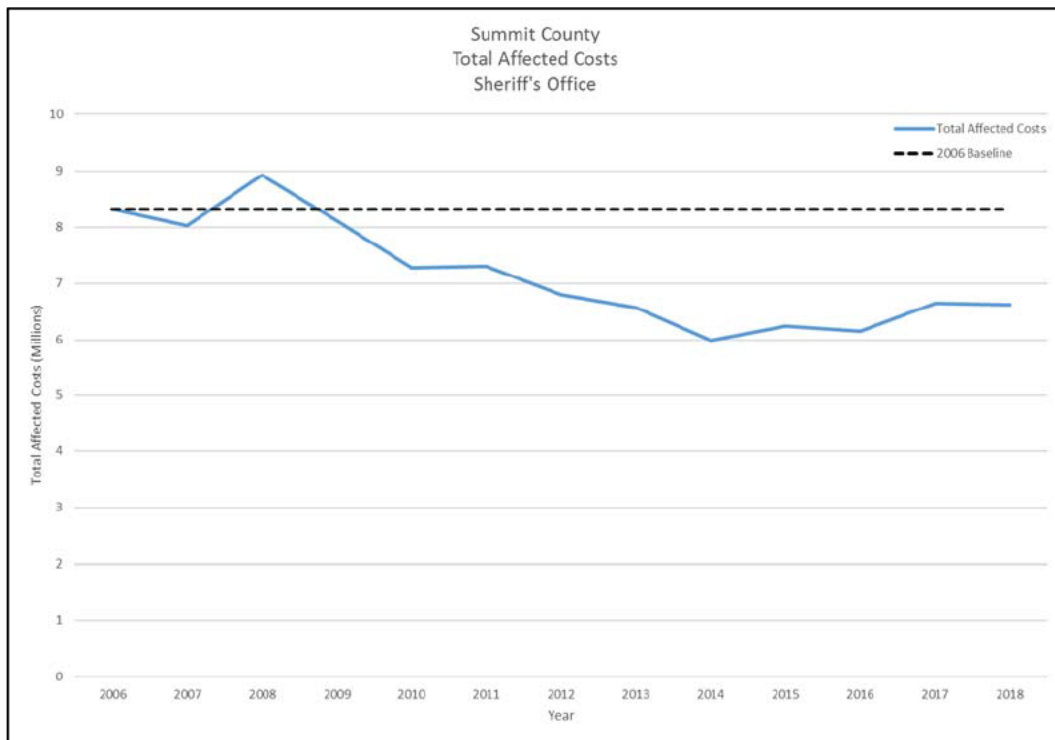
216. Summit County has also seen declining costs. The Sheriff's Office is a division that Professor McGuire focuses on for many of the examples and anecdotes in his report.<sup>321</sup> The Summit County Sheriff's office has total affected costs of \$93 million dollars and make up the third-largest affected division in Professor McGuire's assessment of Summit County.<sup>322</sup>
217. As Exhibit 42 below shows, the county expenditures that Professor McGuire believes are affected by opioids in this division were also decreasing from 2006 levels. The first year of expenditure data includes \$8.3 million in affected costs and by 2018 this number has fallen to \$6.6 million. This decrease of approximately 20% in affected costs conflicts with the Plaintiffs' claim that there was a "need for increased services" and that the Defendants' actions "increased the demand for public services provided by local governments."<sup>323</sup>

<sup>321</sup> See McGuire Damages Report, at ¶¶ 27 and 29.

<sup>322</sup> See McGuire Damages Report, Table IV.8.

<sup>323</sup> See McGuire Damages Report, at ¶¶ 6 and 14.

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**Exhibit 42: Summit County Sheriff's Office Affected Costs**

**Source:** McGuire Damages Report, Table IV.8.

218. In addition to not establishing excess costs, Professor McGuire does not establish that any non-opioid related services are being crowded out by the Alleged Conduct. Professor McGuire's damage analysis is focused on the value of resources that the Bellwether jurisdictions purportedly shifted from alternative uses to combat the harms from the Alleged Conduct.<sup>324</sup> Professor McGuire does not identify any alternative uses for funds, nor does he analyze whether these divisions had any excess capacity to make use of relevant funds.
219. This concept was addressed during Professor McGuire's deposition when he was asked to explain why divisions did not spend their full budgets and instead had a surplus at the end of the year. Specifically, Summit County Addiction Board spent less than its budget for 2017 by approximately \$3.9 million.<sup>325</sup> This example demonstrates that the county division chose not to spend its available funds on any of the other opportunities that Professor McGuire assumes exist.

<sup>324</sup> See McGuire Damages Report, at ¶ 30.

<sup>325</sup> See McGuire Deposition Vol. 1, 346:2-350:14. See SUMMIT\_002057610. See SUMMIT\_000007600.

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220. Professor McGuire alleges that the Defendants’ actions “increased the demand for public services provided by local governments and the provision of these extra services impose costs on local governments.”<sup>326</sup> However, Professor McGuire does not empirically demonstrate an increased demand for services in his damages analysis.
221. Many of these services are tracked in the publicly available Cuyahoga Annual Information Statements and Summit Comprehensive Annual Financial Reports each year. The primary example of this is crime. Professor McGuire identifies several divisions whose services are impacted by the number of overdoses and drug crimes, yet does not provide any evidence of increased demand for these services.
222. As an example of this, the Sheriff’s Office’s responsibilities include “responding to calls for service” and “processing incoming 911 calls for dispatch.”<sup>327</sup> Professor McGuire suggests that the opioid shipments between 2006 and 2018 resulted in an increase in demand for Sheriff Services.<sup>328</sup> This conclusion is at odds with the actual data. Exhibit 43 below shows that the number of 911 call processed by Cuyahoga Emergency Communications System (CECOMS) as reported in the Cuyahoga 2018 AIS in fact declined over the relevant period.

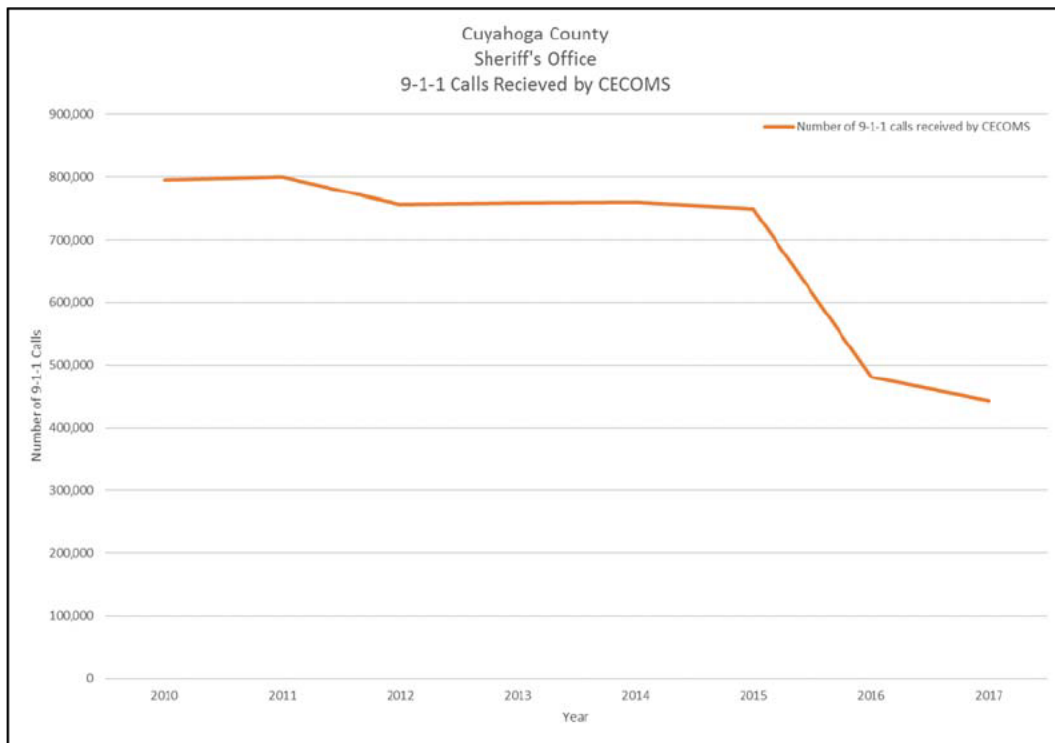
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<sup>326</sup> See McGuire Damages Report, at ¶ 14.

<sup>327</sup> See McGuire Damages Report, at ¶ 54.

<sup>328</sup> See McGuire Damages Report, at ¶ 46.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 43: Cuyahoga County Sheriff's Office 911 Calls Received**

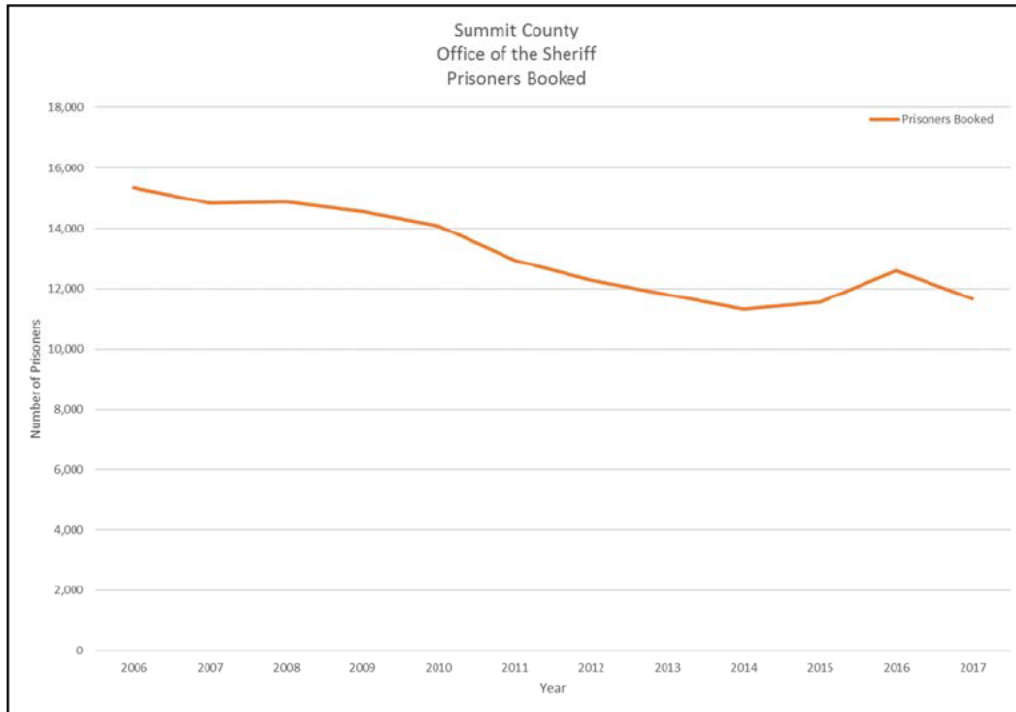
**Source:** Cuyahoga County 2018 AIS, pg. S40.

223. Professor McGuire also alleges that “more people enter the jail and court systems” because of opioids.<sup>329</sup> Although relevant statistics are publically available, Professor McGuire does not cite any in support of his point; nor does he provide any evidence of this increased demand. In fact, the annual operating indicators from the Bellwether Counties refute his assertion. Exhibit 44 and Exhibit 45 demonstrate two examples of this. First, that the number of prisoners booked in Summit County decreases from 2006 to 2017 and second, that the number of prosecutor dispositions in Cuyahoga County decreases from 2010 to 2017.

<sup>329</sup> See McGuire Damages Report, at ¶ 46.

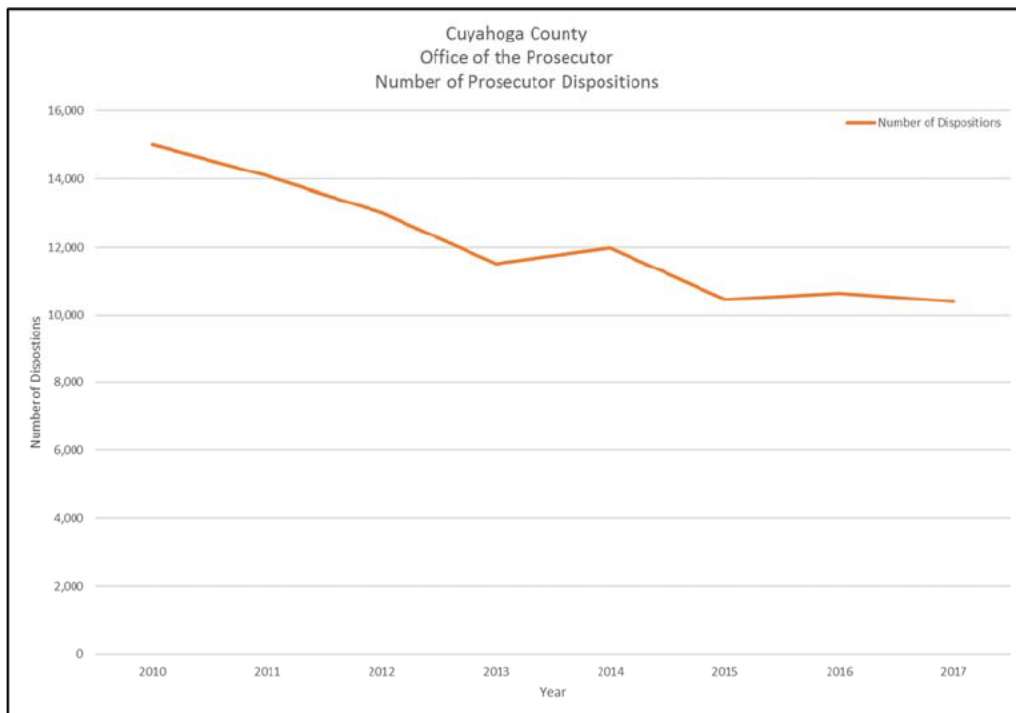
HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**Exhibit 44: Summit County Sheriff's Office Prisoners Booked**



**Sources:** Summit County 2015 CAFR, Table 17 and Summit CAFR 2015, Table 17.

**Exhibit 45: Cuyahoga County Prosecutor's Office Dispositions**



**Source:** Cuyahoga County 2018 AIS, pg. S40.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

224. Professor McGuire does not ground his opportunity cost analysis in a reliable demonstration that alternative services are being neglected or crowded out by the Alleged Conduct. During his deposition Professor McGuire is asked to identify a year between 2006 and 2018 where any of the purportedly affected divisions “created or funded a new position because of opioid problem”, “reassigned any personnel from one department to another because of the opioid problem”, or “chang[ed] the job responsibilities for any employee because of the opioid problem” and he cannot identify any crowding out of services.<sup>330</sup> Professor McGuire does not identify a single instance where any division in Summit County or Cuyahoga County “reallocate[ed] any money from one nonopioid-related program or account in order to address an opioid-related need”.<sup>331</sup> Professor McGuire does not provide any evidence that there are unmet demands for services by the affected divisions that would have been met in the but-for world and therefore has no reliable foundation for his opportunity cost theory.

**C. Professor McGuire’s data collection and treatments are not reproducible**

225. Another important concept in the calculation of damages is the use of evidence-based methods capable of replication. This is a requirement for the proper application of scientific methods: “[t]he reproducibility of scientific experiments and calculations embodies a fundamental aspect of science.”<sup>332</sup>
226. Professor McGuire’s methodology for identifying affected divisions and affected costs in this case is not dependable because it is not reproducible. If the methods Professor McGuire used cannot be reproduced, then they cannot be tested for their reliability.
227. To identify affected divisions, Professor McGuire reviews budget and expenditure information from the Bellwether governments, beginning with divisions representing the largest shares of the Bellwether governments’ overall expenditures.<sup>333</sup> Professor McGuire then reviews the written descriptions of the activities undertaken by each of the largest

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<sup>330</sup> See McGuire Deposition Vol. 2, 495:1–497:7. See McGuire Deposition Vol. 2, 497:18–498:8. See McGuire Deposition Vol. 2, 498:25–501:8. See McGuire Deposition Vol. 2, 501:10–501:22. See McGuire Deposition Vol. 2, 503:8–504:24.

<sup>331</sup> See McGuire Deposition Vol. 2, 506:19–507:24.

<sup>332</sup> See Cicerone, R. “Research Reproducibility, Replicability, Reliability,” National Academy of Sciences (Apr. 27, 2015), at p. 1.

<sup>333</sup> See McGuire Damages Report, at ¶ 51.



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

divisions to determine whether these divisions were likely to have been affected by the opioid crisis.<sup>334</sup> Professor McGuire relies on anecdotes from local officials and articles from *Akron Beacon Journal* in forming his opinion on the divisions most affected by the opioid crisis.<sup>335</sup>

228. Professor McGuire did not have a reliable empirical method for determining which divisions were affected by the opioid crisis. Instead, he relies on the “joint understanding of what it means to be impacted by the opioid crisis” as the basis for his decisions.<sup>336</sup> After forming an understanding based on the review of the budget reports, Professor McGuire reports that “[he] and members of [his] team met with local officials to confirm my understanding of both the activities undertaken by these divisions and whether those activities had been affected by the opioid crisis.”<sup>337</sup> Professor McGuire and his Compass Lexecon team did not use even a loosely structured interview device for the data collection. In the absence of a guiding interview structure, Professor McGuire apparently reached a “joint understanding” with his team of the affected divisions without rigorous support.
229. Importantly, Professor McGuire did not provide any written directions to the member of his team about what data to collect from local officials.<sup>338</sup> Professor McGuire did not personally interview officials that work for the affected divisions and in his deposition further clarified “that these interviews were conducted by members of [his] team.”<sup>339</sup> Professor McGuire cannot verify whether members of his team took notes during the interviews with local officials and admitted to not seeing any notes on these meetings when he was determining the affected divisions.<sup>340</sup> The lack of physical evidence about the meetings with local officials makes them an unreliable source of data.
230. At the next step in his damages estimation, Professor McGuire identifies the relevant costs in each division that he believes would be affected by the community’s use of opioids. Professor McGuire uses expenditure data for Cuyahoga County from the Cuyahoga County

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<sup>334</sup> See McGuire Deposition Vol. 1, 101:22 – 102:20.

<sup>335</sup> See McGuire Damages Report, at ¶ 42.

<sup>336</sup> See McGuire Deposition Vol. 1, 108:15-109:10.

<sup>337</sup> See McGuire Damages Report, at ¶ 51.

<sup>338</sup> See McGuire Deposition Vol. 1, 108:15-109:10.

<sup>339</sup> See McGuire Deposition Vol. 1, 83:3-83:18.

<sup>340</sup> See McGuire Deposition Vol. 1, 77:8-77:13.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

Budget Office and expenditure data for Summit County from the county government for the specific 2006 to 2018 timeframe that Counsel asked him to tabulate.<sup>341</sup>

231. To identify the costs for each affected division that could relate to opioids, Professor McGuire applies the opportunity cost concept to focus on the largest budget line items for each of his selected divisions. By reading each budget line and using his judgement, Professor McGuire identifies which costs he believes to be fixed or variable with respect to opioids.<sup>342</sup> Professor McGuire refers to costs that could move up or down as the composition of services changes as “variable” and considers these to be the affected costs.<sup>343</sup>
232. Professor McGuire describes his methodology for identifying affected costs as “not mechanical” because it did not involve standardized lists and discussions with local officials and instead was a determination made by discussions between Professor McGuire and the his team.<sup>344</sup> During his deposition, Professor McGuire confirms that the methodology he used was to take a list of every cost and break it into variable or fixed based on his judgement and inputs from his team.<sup>345</sup> Professor McGuire indicates that there were some costs for which he was not very confident.<sup>346</sup> He reports that these costs required additional work by his team but he could not identify which costs were confirmed with local officials and which costs were based solely on his judgement.<sup>347</sup> When asked to elaborate further Professor McGuire explains that these were “complicated decisions about something that is mostly conversation” and that it is hard to “reconstruct that beyond talking to the people.”<sup>348</sup> Professor McGuire could not tell “what [he] thought about IT,” “what [he] thought about health insurance costs,” or “whether they would be regarded as fixed or variable.”<sup>349</sup> In order to recreate Professor McGuire’s methodology, one would have to “attempt to talk to the

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<sup>341</sup> See McGuire Damages Report, at ¶ 58.

<sup>342</sup> See McGuire Deposition Vol. 1, 118:22-122:13.

<sup>343</sup> See McGuire Damages Report, at ¶ 56.

<sup>344</sup> See McGuire Deposition Vol. 1, 118:22-122:13.

<sup>345</sup> See McGuire Deposition Vol. 1, 118:22-122:13.

<sup>346</sup> See McGuire Deposition Vol. 1, 122:20-123:14.

<sup>347</sup> See McGuire Deposition Vol. 1, 123:6-123:16.

<sup>348</sup> See McGuire Deposition Vol. 1, 124:23-126:23.

<sup>349</sup> See McGuire Deposition Vol. 1, 124:23-126:23.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

people involved and do the best you can in a reconstruction.”<sup>350</sup> This type of methodology fails to meet even a minimum standard for reliability in an economic damages analysis.

233. Professor McGuire then estimates how much of the costs in each category were incurred in providing activities or services affected by the opioid crisis.<sup>351</sup> The process to do this involved determining which expenditures were related to opioids and which were not. To do this, Professor McGuire either uses the number of full time employees or the salaries by employee type to estimate the costs related to staff in activities that would not have been affected by the increased shipments of opioids (“overhead”).<sup>352</sup> Professor McGuire assumes that any compensation costs except for overhead were affected by the Alleged Conduct.
234. Identifying which compensation costs were overhead or not overhead relied on Professor “[McGuire’s] judgement based on the job activities of the people involved” and discussions with his team.<sup>353</sup> There was no practical method employed to determine which job titles belonged to each category and instead Professor McGuire “made the assumption for labor categories that seemed to be associated kind of fixed costs or overhead-type expenditures that those people would not—the cost associated with those people would not be affected as the opioid crisis went up or down.”<sup>354</sup> During his deposition, Professor McGuire confirmed that determining whether a job title or salary amount is considered overhead was based on his judgement.<sup>355</sup> Professor McGuire refers to this as the “Overhead Adjustment Factor” and applies this factor to his “compensation costs.” This adjustment is specific to each division and requires a different set of assumptions for each calculation.

**D. Professor McGuire does not consider Plaintiffs’ duty to mitigate damages**

235. A reliable measure of economic damages seeks to calculate unavoidable costs incurred by the Plaintiff.<sup>356</sup> One limitation on the amount of recoverable damages is that a party must avoid losses, and thus, has a duty to mitigate and minimize its damages due to the Alleged

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<sup>350</sup> See McGuire Deposition Vol. 1, 133:3-133:17.

<sup>351</sup> See McGuire Damages Report, at ¶ 60.

<sup>352</sup> See McGuire Damages Report, at ¶ 60.

<sup>353</sup> See McGuire Deposition Vol. 1, 117:15-117:23.

<sup>354</sup> See McGuire Deposition Vol. 1, 116:10-116:19.

<sup>355</sup> See McGuire Deposition Vol. 1, 119:6-119:18.

<sup>356</sup> See Allen, Mark et al., “Reference Guide on Estimation of Economic Damages”, p. 461. (“Allen et al.”).

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

Conduct. This limitation follows directly from a concern about economic efficiency requiring that “the injured party should not cause economic waste by needlessly increasing its losses.”<sup>357</sup>

236. Professor McGuire does not attempt to take the Plaintiffs’ burden to mitigate damages into account in his analysis. Professor McGuire should remove the share of harms that could have been avoided had the Plaintiffs implemented similar efforts to mitigate damages. Professor McGuire provides no analysis of the Bellwethers’ response to excess opioid shipments or increasing mortality. Consequently, Professor McGuire’s summation of county expenditures does not meet the standards of reliability for economic damages.

**1. There are several known examples regarding how to mitigate opioid-related harms**

237. There are several examples of county-level mitigation of harms due to the opioid crisis. Dayton, Ohio has experienced a sharp decline in opioid fatalities over the past year. This county (near the Bellwethers) had one of the highest overdose rates in the country in 2017 but, since then, has mitigated those harms by increasing access to treatments and increasing support for users.<sup>358</sup>
238. A recent study from Stanford estimated that “wider availability of naloxone could prevent 21,000 deaths over the next decade — more than expanding access to medications for addiction or reducing painkiller prescriptions could.”<sup>359</sup> The study found that “Naloxone availability, needle exchange, [Medication Assisted Treatment], and psychosocial treatment policies generate gains in [Life Years] and [Quality-Adjusted Life Years] and reduce deaths, without harming any group.”<sup>360</sup>
239. These programs have been adopted by the Bellwethers in recent years, but mortality-related harms might have been mitigated by implementing them sooner. Summit County established

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<sup>357</sup> See Allen et al., pp. 464-465.

<sup>358</sup> See Goodnough, A. “This City’s Overdose Deaths Have Plunged. Can Others Learn From It?,” *New York Times* (Nov. 25, 2018), available at <https://www.nytimes.com/2018/11/25/health/opioid-overdose-deaths-dayton.html>.

<sup>359</sup> See Goodnough, A. “This City’s Overdose Deaths Have Plunged. Can Others Learn From It?,” *New York Times* (Nov. 25, 2018), available at <https://www.nytimes.com/2018/11/25/health/opioid-overdose-deaths-dayton.html>.

<sup>360</sup> See Pitt, A. L., Humphreys, K., & Brandeau, M. L. “Modeling Health Benefits and Harms of Public Policy Responses to the US Opioid Epidemic.” *American Journal of Public Health*, 108:10 (2018), 1394-1400.

## HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

its needle exchange program in June 2016.<sup>361</sup> Cuyahoga County Sheriff's Office trained its deputies on how to use naloxone in August 2017.<sup>362</sup> By not considering the effect earlier implementation of these programs could have on combating harms, Professor McGuire's damages calculation may include expenditures that could have been prevented by Plaintiffs themselves.

## 2. Certain public services are susceptible to economic waste

240. Professor McGuire does not consider that the Bellwethers may have needlessly increased their losses. One division that may have not mitigated expenditures properly is the Department of Children and Family Services. There is information indicating that this area of service is susceptible to counterproductive practices. For example, in 2016, the Arkansas Division of Children and Family Services ("DCFS") hired Hornby Zeller Associates ("HZA") to find out why the foster care population in the state had been "skyrocketing."<sup>363</sup> Similar to the Bellwethers, Arkansas speculated that the opioid crisis was driving the increase in foster care placements.<sup>364</sup>
241. However, in their study, HZA found that the heart of the problem was not a drug crisis.<sup>365</sup> Instead, HZA attributed one of the primary causes to "the way decisions are made about whether and when to remove children from their homes."<sup>366</sup> In that study, HZA reviewed a random sample of 400 care records. Based on that review, HZA found that 22 percent of the removals were probably unnecessary, which translates into at least 300 additional removals

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<sup>361</sup> See Glunt, Nick. "Summit County starts needle exchange program to prevent spread of HIV, hepatitis C", *Akron Beacon Journal* (Jun. 24, 2016), available at <https://www.ohio.com/akron/writers/summit-county-starts-needle-exchange-program-to-prevent-spread-of-hiv-hepatitis-c>. See <https://www.scph.org/counseling/summit-safe-syringe-exchange>.

<sup>362</sup> See Morice, Jane. "Cuyahoga County Sheriff's Office receives free naloxone kits, deputy training", *Cleveland.com* (Aug. 15, 2017), available at [https://www.cleveland.com/metro/2017/08/cuyahoga\\_county\\_sheriffs\\_offic\\_2.html](https://www.cleveland.com/metro/2017/08/cuyahoga_county_sheriffs_offic_2.html).

<sup>363</sup> See Wexler, R. "Needless Removal, Not 'Drug Plague,' Drives Foster Care Numbers Hike in Arkansas," *Youth Today* (Nov. 29, 2016), available at <https://youthtoday.org/2016/11/needless-removal-not-drug-plague-drives-foster-care-numbers-hike-in-arkansas>.

<sup>364</sup> See American Academy of Pediatrics. "Opioid Factsheets - Arkansas." available at [www.aap.org/en-us/advocacy-and-policy/federal-advocacy/Documents/Opioid-StateFactsheets/opioid\\_fs\\_arkansas.pdf](http://www.aap.org/en-us/advocacy-and-policy/federal-advocacy/Documents/Opioid-StateFactsheets/opioid_fs_arkansas.pdf).

<sup>365</sup> See Hornby Zeller Associates, Inc. "Analysis of the Rise in Arkansas' Foster Care Population. Produced for Arkansas Department of Human Services Division of Children and Family Services" (Jun. 2016) ("Hornby Zeller Report").

<sup>366</sup> See Hornby Zeller Report, p. ii.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

which are questionable.<sup>367</sup> HZA provided recommendations to Arkansas DCFS designed to combat removing more children immediately upon investigation, none of which included an increase in budget or funding.<sup>368</sup>

242. This is consistent with problems that have been identified in Ohio. In response to an article cited by Professor McGuire, the executive director of the National Coalition for Child Protection Reform, writes “Foster care increases during a recession only in states that are most prone to confuse poverty itself with ‘neglect.’ That’s why it happened in Ohio, but not in many other states.”<sup>369</sup>
243. This is supported by evidence from the Bellwether counties. For example, “in Akron, Ohio, a grandmother raised her 11-year-old granddaughter despite being confined to a wheelchair with a lung disease. Federal budget cuts cause her to lose housekeeping help. The house becomes filthy. Instead of helping with the housekeeping, child protective services takes the granddaughter away and throws her in foster care for a month.”<sup>370</sup> Decisions like this result in higher costs to the Bellwether governments and results in needless losses.
244. Professor McGuire relies on percentages calculated by Professor Cutler to determine what share of foster care harms are attributable to the Alleged Conduct. These percentages include all opioid use and do not take into account whether these opioids were prescribed or whether these opioids were taken as a part of a recovery program. The HZA report found that the Arkansas DCFS “took holds on newborns after the mother tested positive for illegal substances even when the parents were forthcoming and cooperative with the investigation and there were no other safety concerns regarding the family or the family’s home.”<sup>371</sup> Professor McGuire did not do any analysis of whether this type of waste was happening in the Bellwethers and if so, how it affects expenditures in the actual and the but-for worlds.
245. If Professor McGuire studied the parallels between the Arkansas case study and the Bellwether counties, he might have determined that the Plaintiffs did not meet their duty to

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<sup>367</sup> See Hornby Zeller Report, p. ii.

<sup>368</sup> See Hornby Zeller Report, p. 24.

<sup>369</sup> See Wexler, R. “Richard Wexler: Child welfare has a foster care addiction.” *Akron Beacon Journal* (Jan. 7, 2018), available at <https://www.ohio.com/akron/editorial/richard-wexler-child-welfare-has-a-foster-care-addiction>.

<sup>370</sup> See Committee on Ways and Means U.S. House of Representatives. “To Review Proposals to Improve Child Protective Services”, May 23, 2006, p.81.

<sup>371</sup> See Hornby Zeller Report, p. 6.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

mitigate damages in his largest category of affected costs. Instead, Professor McGuire ignored the Plaintiffs duty to mitigate and therefore cannot reliably calculate the unavoidable damages in this case.

**E. Professor McGuire does not adequately consider the role of the public sector in Professor Cutler's measurement of harms**

246. As discussed in Section V.E above, Professor Cutler does not consider the role of the public sector in his measurement of harms due to Defendant Alleged Conduct. This causes Professor McGuire to overstate damages to the Bellwethers because none of the Plaintiffs' Economics Experts properly apportion harms between the Defendants and the Public Sector.
247. Professor Cutler “doesn't give specifics on any specific entity that should have done anything” and therefore captures the shared responsibility for all entities including Plaintiffs, Defendants, and non-Defendants.<sup>372</sup> The non-Defendants include the Federal and State public sector entities that shared responsibility for monitoring and regulating the shipments that Professor Cutler alleges led to harm. All of the percentages that Professor Cutler calculates in his report contain an aggregate amount of harm and include the actions (or inaction) of DEA, FDA, State of Ohio, PDMP's, and law enforcement.<sup>373</sup>
248. Professor McGuire does not attempt to make any modification to Professor Cutler's percentages to account for the fact they are aggregate harms for Defendants and Non-Defendants.<sup>374</sup> Professor McGuire simply uses the percentages given to him as an input and believes that the question of incorporating third-party conduct is better directed to “to Rosenthal or Cutler who were attempting to associate shipments or harms to particular behavior.”<sup>375</sup>
249. Professor McGuire's decision to use unmodified percentages from Professor Cutler results in a calculation that includes harms that are not solely the result of the Alleged Conduct. As I discussed in the previous section, these harms also include actions taken by the Plaintiffs that propagated or at the very least did not mitigate the damages. Professor McGuire's use

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<sup>372</sup> See Cutler Deposition Vol. 1, 90:18-91:1.

<sup>373</sup> See Cutler Deposition Vol. 1, 97:8-98:14.

<sup>374</sup> See McGuire Deposition Vol. 1, 384:14-385:21.

<sup>375</sup> See McGuire Deposition Vol. 1, 198:16-199:14.



HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

of Professor Cutler’s unreliable percentage harms means that the Plaintiffs cannot accurately apportion damages between the Alleged Conduct and conduct of the Public Sector.

**F. Professor McGuire’s methodology cannot disaggregate damages between marketing and diversion allegations or apportion damages among Defendants**

250. Lastly, a proper economic damages analysis must connect Plaintiffs’ theory of causation to the facts of the case and demonstrate robustness to important alternative considerations.<sup>376</sup> Professor McGuire’s calculations cannot be done without the inputs from Professor Rosenthal and Professor Cutler’s reports. He cannot opine on alternative considerations about causality because he can only speculate about how factors other than the ones he implicitly assumes would affect his damages.
251. There are at least two specific assumptions that Professor McGuire relies upon for which he is not able to opine on any alternative considerations in this case without relying on the analyses of Professor Rosenthal and Professor Cutler. Professor McGuire is not able to apportion damages between either 1) prescription and illicit opioids or 2) any individual Defendant without new inputs from the other Plaintiffs’ Experts.
252. First, Professor McGuire cannot distinguish which costs relate specifically to prescription opioids and doing so would be purely speculative. For example, if the court finds that Defendants are only liable for harms related to prescription opioids that were taken as prescribed, Professor McGuire cannot accurately estimate damages. In his deposition, Professor Cutler confirms an example that “if a jury finds that the Defendants cannot be held responsible for harms caused by illicit opioids, [he] can’t identify the portion of treatment and addiction services that are limited to licit opioids,” and therefore Professor McGuire cannot calculate damages.<sup>377</sup> Professor McGuire uses percentages given to him by Professor Cutler that contain “opioid deaths that could be because of illicit or licit opioids” and cannot estimate what shares of harms are the result of Defendants’ actions.<sup>378</sup>

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<sup>376</sup> See “Litigation Services Handbook” Chapter 3, Section 3.3, p. 15.

<sup>377</sup> See Cutler Deposition Vol. 1, 253:20-254:1.

<sup>378</sup> See McGuire Deposition Vol. 1, 282:3-284:8.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

253. The evidence provided by other Plaintiffs' Economics Experts does not support including the share of harms from both illicit and licit opioid from 2006 to 2018.<sup>379</sup> There is no basis in the relevant literature or evidence presented in this case that indicates that Defendants' actions impacted illicit opioid mortality from 2006 to 2010, and Professor McGuire cannot remove damages related to illicit mortality from his analysis in these years based on the inputs from Professor Cutler.
254. Second, Professor McGuire cannot distinguish which costs are due to manufacturer Defendants, distributor Defendants, pharmacy Defendants, or anyone else. Instead, Professor McGuire provides eight approaches to damages, but these approaches are not cumulative, nor do they attempt to apportion the damages in any way. Professor McGuire calculates "an estimate of the total damages without attempting to attribute them to any of the particular defendants."<sup>380</sup> Professor McGuire simply sums all of the expenditures for each of the affected divisions; he cannot attribute that amount "to particular defendants, particular distributor defendants nor [does he] attempt to allocate it even between the group of distributor defendants and the group of manufacturer defendants."<sup>381</sup> If the court decides that any particular Defendant, or group of Defendants are more or less responsible for the harms to the Bellwethers, Professor McGuire cannot calculate a damages number without the help of both Professor Rosenthal and Professor Cutler.
255. Apart from not having a methodology to apportion damages amongst particular Defendants or types of Defendants, Professor McGuire lacks any empirical approach to assigning damages to various allegations in this case. Professor McGuire confirms in his deposition that he does not "offer calculations of damages that distinguish between damages arising from people using prescription opioids that were prescribed to them versus damages arising from people using prescription opioids that were diverted and weren't prescribed to them" and that he does not break out damages into these categories.<sup>382</sup> This means that if the court finds the Defendants responsible for only a portion of the allegation in this case, Professor McGuire cannot reliably calculate the relevant damages.

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<sup>379</sup> See Gruber Report, at ¶ 95. See Cutler Report, at ¶ 50.

<sup>380</sup> See McGuire Deposition Vol. 1, 188:6-189:6.

<sup>381</sup> See McGuire Deposition Vol. 1, 196:17-196:24.

<sup>382</sup> See McGuire Deposition Vol. 1, 257:23-258:16.

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256. Professor McGuire relies on Professors Rosenthal and Cutler for both causation and the share of harms attributable to the Alleged Conduct. Without their reports, he cannot calculate damages for alternative considerations in this case and thus, he has no separate foundation for developing reliable opinions responsive to alternative assumptions about conduct and causality.

## VII. Conclusions

257. My evaluation and analyses have identified numerous parts of Plaintiffs' Economics Experts' reports where sources of error are substantial and undermines the Economic Framework. Importantly, the uncertainties inherent in the methodologies used by Plaintiffs' Economics Experts accumulate and cascade through the causality and damages analyses undermining any confidence that the final results are reliable within a reasonable degree of professional certainty.
258. The Alleged Conduct is evaluated within a highly complicated set of processes and is combined with other conduct and events over a long period of time. The reality of the difficulty to understand the "how, why, and when" of the opioid epidemic has been noted by the National Academies of Sciences, Engineering, and Medicine:<sup>383</sup>

[T]he professional societies, insurers, health care organizations, pharmaceutical manufacturers, and state and federal agencies collectively responsible for shaping prescribing practices should attend to the multiple weaknesses in the nation's health system that led to this epidemic... law enforcement agencies will continue to be responsible for curtailing trafficking in illegally manufactured opioids, most recently the low-priced, high-potency fentanyl manufactured in clandestine labs domestically and also streaming into the country from abroad.

259. Even with their attempts at abstraction and simplification within the Economic Framework, Plaintiffs' Economics Experts have not proved that they can isolate the impact and damages, if any, caused by Alleged Conduct given the many confounding factors and processes at issue in this matter. Based on my analysis, I have reached a number of specific conclusions:

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<sup>383</sup> See National Academies of Sciences, Engineering, and Medicine, "Preface - Pain Management and the Opioid Epidemic," National Institutes of Health, (July 13, 2017).

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**A. The Economic Framework uses associations to make inferences and estimate damages without proving causality**

260. I have identified numerous instances in which Plaintiffs' Economics Experts use associations to make inferences and estimate outcomes, impacts, and damages without proving causality. Plaintiffs' Economic Experts ignore many influences that are not derived from the Alleged Conduct or which are complicated by the clear roles of non-Defendants. These deficiencies in Plaintiffs' Economics Experts' analyses render their results incapable of supporting reliable causality opinions.

**B. The Economic Framework suffers from data and knowledge gaps that are being addressed through disregard, speculation, and anecdotal information as well as inconsistencies across baselines and estimation periods**

261. I have demonstrated that each set of analyses by Plaintiffs' Economics Experts that contributes to the Economic Framework suffers from severe data and knowledge gaps that are inadequately resolved. These information gaps render their results speculative.

**C. Plaintiffs' Economics Experts have imposed certain artificial assumptions to simplify the characterization of the but-for world undermining the reliability of their results**

262. I have shown the artificial nature of key assumptions made by Plaintiffs' Economics Experts purportedly to simplify the crucial characterization of the world absent the Alleged Conduct. I have also demonstrated the implications of a number of these assumptions and that they render Plaintiffs' Economics Experts' opinions on impacts and damages unreliable. Due to the oversimplified assumptions made by Professors Rosenthal and Cutler, Professor McGuire's final estimation of damages relies on inadequate support to prove Plaintiffs' allegations. In addition, he cannot provide an economically sound basis to attribute and apportion causality among Defendants.

**D. The uncertainties within Plaintiff Economics Experts' analyses is compounded and expanded through the stages of the Economic Framework**

263. Importantly, the analyses of Plaintiffs Economics Experts' are consecutively related. I have shown that there are substantial uncertainties at each link of the Economic Framework (from Rosenthal to Cutler to McGuire). Moreover, my review indicates that these uncertainties are

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

unlikely to be offsetting. As a result, the uncertainty of the final damages calculations that, by design in the Economic Framework, rely on numerous preceding framework components will be at least as great, and more likely, much greater than the uncertainty of any single preceding component. Plaintiffs Economics Experts have not adequately addressed the compounding and expanding uncertainties in the design of the Economic Framework. The implication of these cascading uncertainties is that they affect the reliability of the estimated opioid volumes, harms, and impacts in the but-for world, and the causality opinions and damage calculations derived from them.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

Dated: May 10, 2019

A handwritten signature in blue ink, reading "Robin Cantor", written over a horizontal line.

Robin Cantor, Ph.D.

## ATTACHMENT 1 Curriculum Vitae



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### SUMMARY

Dr. Robin Ann Cantor is a managing director in Berkeley Research Group's Washington, DC, office. She has a Ph.D. in economics from Duke University and a B.S. in mathematics from Indiana University of Pennsylvania. Dr. Cantor has more than 30 years of experience in environmental, health, and energy economics, applied economics, statistics, risk management, and insurance claims analysis.

Before joining BRG, Dr. Cantor led practice groups at Exponent, Inc., and Navigant Consulting; and assisted companies and financial institutions with analysis to better understand environmental, health, and other product liability exposures. She has also acted as a principal and managing director of the Environmental and Insurance Claims Practice at LECG, LLC; and program director for Decision, Risk, and Management Sciences, a research program of the National Science Foundation; and held senior research appointments at Oak Ridge National Laboratory.

Dr. Cantor has a faculty appointment in the graduate part-time program in engineering of the Johns Hopkins University. She was president of the Society for Risk Analysis in 2002, and from 2001 to 2003 served as an appointed member of the Research Strategies Advisory Committee of the U.S. Environmental Protection Agency's Science Advisory Board. Dr. Cantor is a fellow of the Society for Risk Analysis and past president of the Women's Council on Energy and the Environment. She also serves or has served on science review and advisory boards for the Climate Decision Making Center at Carnegie Mellon University, Johns Hopkins University's graduate part-time program in Environmental Engineering, Science, and Management, the National Center for Environmental Decision Making Research, Carnegie Council for Ethics in International Affairs, National Oceanic and Atmospheric Administration, National Academy of Public Administration, and Center for International Earth Science Information Network.

Dr. Cantor's consulting practice focuses on economics at the interface of science and technology. Many of her projects involve science-based economic analysis used in litigation support, expert testimony, risk assessment, and other advisory services addressing energy, environmental, and health issues. Dr. Cantor's testimonial experience includes analysis of market share theories of product liability, fair market compensation in eminent domain matters, healthcare reimbursement, economic damages, product liability estimation in bankruptcy matters and insurance disputes, asbestos settlements, premises and product claims, cost contribution allocation in Superfund disputes, derailment risks, reliability of statistical models and estimation methods, and class certification issues.

Dr. Cantor has prepared expert reports that address economic issues in healthcare and energy markets, antitrust, commercial practices and contracts, intellectual property, employment discrimination, false advertising, regulation, and other areas of product and market analysis. Dr. Cantor has submitted analysis, testimony, and affidavits in federal arbitration, regulatory and Congressional proceedings, and





state and federal courts. Her publications include refereed journal articles, book chapters, expert reports, reports for federal sponsors, a book on economic exchange under alternative institutional and resource conditions, and an edited book on product liability published by the American Bar Association.

## **EDUCATION**

Ph.D., Economics     Duke University, 1985  
B.S., Mathematics     Indiana University of Pennsylvania, 1978

## **PREVIOUS POSITIONS**

Principal Scientist, Exponent, Inc. 2008–2013

Managing Director, Navigant, 2004–2008

Lecturer, Graduate Program, Johns Hopkins University, Engineering and Applied Science Programs for Professionals, Program in Environmental Engineering, Science and Management, 1996–present

Principal and Managing Director, LECG, 1999–2004

Senior Managing Economist, LECG, 1999

Managing Economist, LECG, 1996–1998

Member, U.S. Environmental Protection Agency, Science Advisory Board, Research Strategies Advisory Committee, 2001–2003

Program Director, Decision, Risk, and Management Science, National Science Foundation, 1992–1996

Coordinator, NSF Human Dimensions of Global Change, 1992–1996

Project Manager, Oak Ridge National Laboratory, 1990–1991

Technical Assistant to the Associate Director, Advanced Energy Systems, Oak Ridge National Laboratory, 1989–1990

Group Leader, Social Choice and Risk Analysis Group, Energy and Economic Analysis Section, Oak Ridge National Laboratory, June 1987–1989

Research Staff, Energy and Economic Analysis Section, Oak Ridge National Laboratory, Oak Ridge National Laboratory, October 1982–1987

Consultant, Indonesian Energy Project, Harvard Institute for International Development, July 1987

Visiting instructor, North Carolina Central University, Spring 1982



## PROFESSIONAL HONORS

Who's Who Legal: Insurance & Reinsurance Expert Witnesses 2015 - 2019  
President, Women's Council on Energy and the Environment, 2015 - 2017  
Fellow, Society for Risk Analysis, 2002  
President, Society for Risk Analysis, 2002  
YWCA Tribute to Women Award for Business and Industry, 1990  
Society for Risk Analysis Presidential Recognition Award, 2008  
Society for Risk Analysis Outstanding Service Award, 1999  
NSF Director's Award for Superior Accomplishment, 1996  
NSF Special Act Award, 1995  
NSF Director's Award for Program Officer Excellence, 1994  
Oak Ridge National Laboratory Significant R&D Accomplishment Award, 1993  
Martin Marietta Special Achievement Award, 1990  
Martin Marietta Special Achievement Award, 1989  
Martin Marietta Energy Systems Significant Event Award, 1988  
C.B. Hoover Scholar, 1980–1981  
Mellon Fellowship, 1978–1981

## PUBLICATIONS

Cantor, R., Klenk, J. Economic Analysis of Class Certification. In: International Comparative Legal Guide to: Class and Group Actions 2019, Global Legal Group, November, 2018.

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Cantor RA, Jones D, Lieby P, Rayner S. Policies to encourage private sector responses to potential climate change. In: *Energy Markets in the 1990s and Beyond*. Finizza A, Weyant JP (eds), IAEE, Washington, DC, 1989.

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## OTHER PUBLICATIONS

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## TECHNICAL MANUSCRIPTS

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Menzie C, Cantor RA, Boehm P, Bailey JR. An approach to business vulnerability and risk assessments related to climate change. SPE Paper Number SPE-127083-PP, November, 2009.

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Rebuttal Verified Statement with Gordon C. Rausser for CSX Corporation and CSX Transportation, Inc., Norfolk Southern Corp., and Norfolk Southern Railway Co., Control and Operating Leases/Agreements, Conrail Inc. and Consolidated Rail Corp., Railroad Control Application, Applicants’ Rebuttal Vol. 2B of 3, December, 1997.

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Markets, Distribution, and Exchange after Societal Cataclysm, Oak Ridge National Laboratory, ORNL-6384, November 1989 (with S. Rayner and S. Henry).

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Evaluation of Implementation, Enforcement and Compliance Issues of the Bonneville Model Conservation Standards Program, Vol. I and II, ORNL/CON-263, July 1989 (with Steve Cohn).

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Clinch River Breeder Reactor: An Assessment of Need for Power and Regulatory Issues, ORNL/TM-8892, September 1983 (with D. M. Hamblin et al.).

## **SELECTED PRESENTATIONS**

Cantor R., Bates H., Mackoul, C. Economic Origins of the Opioid Crisis, Society for Risk Analysis, 2018 Annual Meeting, New Orleans, LA, December 2-6, 2018.

Cantor R, Bates H. Statistical Origins of the Opioid Crisis, Invited presentation, PLAC 2018 Spring Conference, Washington DC, April 11-13, 2018.





Cantor R. Survey Methodology and the Science of Risk: Limitations and future directions, Society for Risk Analysis-Europe, 2017 Annual Meeting, Lisbon, PT, June 18-21, 2017.

Cantor, R. Alternative Dispute Resolution to Mass Claims, 1<sup>st</sup> Annual Class Action Money & Ethics Conference, New York City, May 1, 2017.

Cantor R, Cross P, Mackoul C. Challenges to product labeling: Consumer protection or opportunism? Society for Risk Analysis, 2016 Annual Meeting, San Diego, CA, December 11–14, 2016.

Cantor R, The role of the economist, ABA Section on Antitrust Law, Seminar and Teleconference, Class Action Fundamentals for Antitrust Litigators, Washington, DC, May 5, 2016.

Cantor R, Meer, S, Tyler, C. What drives physician testing for pain medication compliance—risk or reward? Society for Risk Analysis, 2014 Annual Meeting, Denver, CO, December 7–11, 2014.

Schmier J, Cross P, Cantor R, Lau E, Steffey D, Watson W. Bias in relative accuracy metrics. International Poster Presentation at the Society of Pharmacoeconomics and Outcomes Research 18th Annual International Meeting, New Orleans, LA, May 18–22, 2013.

Cantor RA. Entrepreneurship vs. Philanthropy: What drives women in the workplace? Women's Council on Energy and the Environment, Brown-bag Luncheon, Washington, DC, February 21, 2013.

Cantor RA. The Future of Energy Policy in America. Public Leadership Education Network, Women & Science & Technology Seminar, Washington, DC, January 8, 2013.

Cantor R, Schmier J, Hulme-Lowe C, Meer S. What will it really cost? Hidden indirect costs and countervailing risks in regulatory impact assessment. Society for Risk Analysis, 2012 Annual Meeting, San Francisco, CA, December 9–12, 2012.

Cantor R, Schmier J, Levine J. Climate change and human health: A sleeping giant? Society for Risk Analysis World Congress on Risk 2012: Risk and Development in a Changing World. Sydney, Australia, July 18–20, 2012.

Cantor R, Meer S. Product liability: An overview of the emerging issues. Society for Risk Analysis World Congress on Risk 2012: Risk and Development in a Changing World, Sydney, Australia, July 18–20, 2012.

Cantor RA, Menzie CA, Bremser AW, Deardorff TL, Hulme-Lowe CK, Wickwire WT. Seeing the forest through the trees: NRD and dynamic ecosystems. Poster Presentation at the Society for Risk Analysis, 2011 Annual Meeting, Charleston, SC, December 4–7, 2011.

Cantor RA. Evaluating vulnerabilities and identifying emerging risks. Invited presentation, The Conference Board EHS Legal Counsel Meeting, Houston TX, January 15–16, 2009.



Cantor RA. Using exposure science to ascertain asbestos liabilities. Invited CLE presentation, Business Valuation Resources, LLC Teleconference, November 18, 2008.

Cantor RA. Weather and temperature: Emerging health issues for US companies. REBEX 2008, Wheeling IL, October 23–24, 2008.

Cantor RA. Asbestos risk transfers: Unlocking value by walling off asbestos liabilities. Invited CLE session at Willkie Farr & Gallagher, New York, NY, June 4, 2008.

Cantor RA. The future of asbestos—New techniques for unlocking value by selling liabilities to investors. Mealey's™ Teleconference, March 25, 2008.

Cantor RA. Update on other U.S. long-tailed product liabilities. Invited presentation, 4th International Asbestos Claims & Liabilities Conference: The Practical Guide to Litigating, Settling and Managing Asbestos Claims, London, January 30-31, 2008.

Cantor RA. Tax or cap: What are the real differences for carbon policy in the US? Invited session and presentation, McDermott Will & Emery 10th Annual Energy Conference, Washington DC, October 9-10, 2007.

Cantor RA. Managing nanotechnology's life cycle risks responsibly. Invited ALI-ABA teleconference, June 27, 2007.

Cantor RA. Carbon emissions—Planning for the change. Invited teleconference, Environmental Law Network, June 15, 2007.

Cantor RA. Liability estimation and the historical future. Invited presentation, Mealey's™ Asbestos Bankruptcy Conference, Chicago, IL, June 7-8, 2007.

Cantor RA. Renewables and the value proposition for carbon credits. Invited presentation, McDermott Will & Emery 9th Annual Energy Conference, Washington DC, October 19-20, 2006.

Cantor RA. The ABCs of the value proposition for carbon credits. Invited presentation, the Environmental Trading Congress, New York, NY, July 24-25, 2006.

Cantor RA, Lyman M. Liability estimation in U.S. bankruptcy cases. London Underwriting Centre, London, UK, January 10, 2006.

Cantor RA, Lyman M. The status of the FAIR Act. London Underwriting Centre, London, UK, January 10, 2006.

Cantor RA. Economic appraisal of ecological assets. Invited presentation, U.S. Environmental Protection Agency Science Advisory Board "Science and the Human Side of Environmental Protection" Series, Washington, DC, July 6, 2002.

Cantor RA. Scientists and Homeland Security—The relevance of risk analysis. Invited presentation, Council of Scientific Society Presidents, Washington, DC, May 2002.



Cantor RA. NRD rules and economics. Invited presentation, Environmental and Admiralty Law Committees of the Association of the Bar of the City of New York, December 7, 2000.

Cantor RA. Revealed preferences and environmental risks: Lessons learned from two policy debates. Annual Meetings of the Society For Risk Analysis, Phoenix, AZ, December 8, 1998.

Cantor RA. Valuing environmental impacts: Lessons learned from the natural resource damage debate. Invited Paper, Society of Environmental Toxicology and Chemistry, 19th Annual Meeting, November 19, 1998.

Cantor RA. How will climate change affect economics and politics? Invited panel speaker, Policy and Politics of Climate Change, ABA Section of Natural Resources, Energy, and Environmental Law Fall Meeting, October 8, 1998.

Cantor RA. Natural resource damage rules: A search for the path of least resistance in value disputes? George Washington University Seminar Series on Environmental Values and Strategies, September 1997.

Cantor RA. Rethinking the science of risk management: Changing paradigms of the process and function. Operations and Information Management Department Workshop, Wharton School of the University of Pennsylvania, November 1995.

Cantor RA, Arkes H. Interdisciplinary perspectives on experimental methods. 1995 Meetings of the American Economic Association, January 1995.

Cantor RA. Risk management: Four different views. Invited presentation, The Conservation of Great Plains Ecosystems Symposium, April 1993.

Cantor RA. Human dimensions of global change: A white paper on the USGCRP research programs. National Academy of Sciences Board on Global Change, November 1993.

Cantor RA, Rayner S. Changing perceptions of vulnerability. Invited paper, NCAR/UCAR Summer Institute on Industrial Ecology and Global Change, July 17-31, 1992.

Cantor RA. Should economic considerations limit the conservatism of risk assessment? Invited paper, Workshop of the International Society of Regulatory Toxicology and Pharmacology on Risk Assessment and OMB's Report on its Application in Regulatory Agencies, Washington, DC, June 11, 1991.

Cantor RA. Beyond the market: Recent regulatory responses to the externalities of energy production. Annual Meetings of the National Association of Environmental Professionals, Baltimore, MD, April 30, 1991.

Cantor RA. Understanding community preferences at Superfund sites. National Meeting of EPA Community Relations Coordinators, Chicago, IL, April 4-6, 1990.



Cantor RA. Methodological myths and modeling markets: A common framework for analyzing exchange. Second Annual International Conference on Socio-Economics, Washington, DC, March 1990.

Cantor RA, Schoepfle GM, Szarleta EJ. Sources and consequences of hypothetical bias in economic analyses of risk behavior. 1989 Meetings of Society for Risk Analysis, October 1989.

Cantor RA, Jones D, Lieby P, Rayner S. Policies to encourage private sector responses to potential climate change. 1989 Meetings of International Association of Energy Economists, October 1989.

Cantor RA, Szarleta EJ. The experimental approach in public policy analysis: precepts and possibilities. Public Choice Society and Economic Science Association Annual Meetings, Orlando, FL, March 17-19, 1989.

Cantor RA, Rayner S. Global disaster management: Developing principles for research. 1988 Meetings of the Association for Public Policy Analysis and Management, October 1988.

Cantor RA. Implementation and enforcement issues from early adopter experience. Regional Evaluation Network, Northwest Power Planning Council, Portland, OR, June 1988.

Cantor RA. Using information from toxic-tort litigation to value the health and safety consequences of regulatory decisions. Public Policy Workshop, the Department of Economics and Waste Management Research and Education Institute, University of Tennessee, Knoxville, TN, February 1988.

Cantor RA, Bishop R, Jr. Valuing safety and health effects in regulatory decisions: A revealed-preference approach. 1987 Annual Meeting of the Society for Risk Analysis, November 3, 1987.

Cantor RA. Government intervention and technology prices: The CANDU example. Invited paper, WATTEC Conference, Knoxville, TN, February 19, 1987.

Cantor RA. Fairness hypothesis and managing the risks of societal technology choices. 1986 Winter Annual Meeting of the American Society of Mechanical Engineers, Anaheim, CA, December 10-12, 1986.

Cantor RA. A retrospective analysis of technological risk: The case of nuclear power. Invited paper, Center of Resource and Environmental Policy Workshop Series, Vanderbilt University, Nashville, TN, December 4, 1986.

Cantor RA, Petrich C, Mercier J-R. Evaluation of a large-scale charcoal project in Madagascar: Attacking the deforestation problem from the supply side. 1986 IAEE North American Conference, Cambridge, MA, November 19-21, 1986.

Cantor RA, Rayner S. Tools for the job: Choosing appropriate strategies for risk management. 1986 Annual Meeting of the Society for Risk Analysis, Boston, MA, November 9-12, 1986.



Cantor RA, Rayner S. Thinking the unthinkable: Preparing for global disaster. 1986 Annual Meeting of the Society for Risk Analysis, Boston, MA, November 9-12, 1986.

Cantor RA, Rayner S, Braid B. The role of liability preferences in societal technology choices: Results of a pilot study. 1985 Annual Meetings of Society for Risk Analysis, Washington, DC, October 8, 1985.

## **CONFERENCE PARTICIPATION**

Co-Chair, Class Action Money & Ethics 2018, New York City, May 2018.

Chair, Finance Committee "Fourth World Congress on Risk," Singapore, July 2015.

Invited panelist for "An Integrated Risk Framework for Gigawatt-Scale Deployments of Renewable Energy: The Wind Energy Case Study," 2009 Annual Meeting for the Society for Risk Analysis, Baltimore, MD, December 9, 2009.

Invited session organizer and panelist for "Global Warming and Greenhouse Gas Controls: What do they mean for you?" 2008 Annual Meeting of the National Association of Publicly Traded Partnerships, Washington DC, June 26, 2008.

Co-chair, "Second World Congress on Risk," Guadalajara, Mexico, June 2008.

Invited panelist for "Climate Litigation: The Next Asbestos or the Next Y2K?" ABA Section of Litigation Annual Conference, Washington DC, April 17, 2008.

Invited panelist for "Business of Mitigation: Carbon Offsets and Trading," Oxford University Capstone Conference, Oxford, UK, September 10, 2007.

Panelist for "Issues Concerning Implementation," at the Public Forum on OMB's Proposed Risk Assessment Bulletin: Implications for Practice Inside and Outside Government, sponsored by Society for Risk Analysis, Society of Environmental Toxicology and Chemistry in North America, Society of Toxicology, and International Society of Regulatory Toxicology and Pharmacology.

Session Chair, "Challenges Facing Industrial Countries," with key-note speeches by Philippe Busquin, EU Commissioner for Research, and Dr. John Graham, Administrator of the US Office of Information and Regulatory Affairs, Inaugural Conference of the International Risk Governance Council, Geneva, Switzerland, June 29, 2004.

Co-Chair, "First World Congress on Risk," Brussels, Belgium, June 2003.

Chair of the Organizing Committee, 2001 Annual Meetings for the Society for Risk Analysis.

Member of the Organizing Committee, Risk and Governance Symposium, Society for Risk Analysis, June 2000.

Organizing Committee Member for the 1996, 1997, 1998, and 2002 Annual Meetings of the Society for Risk Analysis.



Panelist for Net Environmental Benefits Assessment for Restoration Projects after Oil Spills, Conference on Restoration for Lost Human Uses of the Environment, Washington, DC, May 1997.

Session Organizer and Chair for Cost Benefit Analysis and Risk Assessment at the 1996 Annual Meeting of the Society for Risk Analysis.

Panelist for Challenges in Risk Assessment and Risk Management sponsored by The Annenberg Public Policy Center of the University of Pennsylvania at the National Press Club, Washington, DC, May 16, 1996.

Panelist for Media and Risk in a Democracy: Who Decides What Hazards Are Acceptable? At the 1995 Annual convention of the Association for Education in Journalism and Mass Communication.

Session Organizer and Co-Chair for Experimental Methods: Insights from Economics and Psychology at the 1995 Meetings of the American Economic Association.

U.S. Organizer for the Third Japan-U.S. Workshop on Global Change Modeling and Assessment: Improving Methodologies and Strategies, Hawaii, October 1994.

Cluster Organizer for three sessions on Competitiveness at the Fall Meeting of the Operations Research Society of America/The Institute of Management Sciences, 1994.

Roundtable Panelist for Risk Communication Research: Defining Practitioner Needs at the 1994 Meetings of the Society for Risk Analysis.

Workshop Organizer for Organizational Transformation and Quality Systems, National Science Foundation, 1993.

Session Chair and Organizer for the NSF/Private Sector Research Initiative Projects at the 1992 Meetings of the Society for Risk Analysis.

Roundtable Panelist for the EPA Session on Risk Communication at the 1990 Meetings of the Society for Risk Analysis.

Session Chair and Organizer for the Computer Assisted Market Institutions Session at the Advanced Computing for the Social Sciences Conference, April 1990.

Discussant for the Issues in LDC Public Finance Session at the 1988 Meetings of the American Economic Association.

Session Chair and Organizer for Social Science Innovations in Risk-Analysis Methods, Special Session at the 1988 Meetings of the Society for Risk Analysis.





## **ADVISORY AND OTHER APPOINTMENTS**

Advisory Board Member, Climate and Energy Decision Making Center, Carnegie Mellon University, June 2011-present

National Research Council Committee to Review the Department of Homeland Security's Approach to Risk Analysis, November, 2008–2010

Member, Advisory Group for the Joint Global Change Research Institute, a collaboration between Pacific Northwest National Laboratory and the University of Maryland, 2004–2008

Member, Planning Committee for a study to evaluate the U.S. National Assessment of the Potential Consequences of Climate Variability and Change, coordinated through Carnegie Mellon University, 2004

Neutral technical panelist working with Arbitrator Anthony Sinicropi on negotiation issues related to the pilots' compensation contract. Retained by US Airways and the Air Line Pilots Association (ALPA), 2001 and 2002

Advisory Board Member, Johns Hopkins University Graduate Part-Time Program in Environmental Engineering and Science, 2000–2004

Planning Committee Member, Carnegie Council on Ethics and International Affairs Long Term Study of Culture, Social Welfare, and Environmental Values in the U.S., China, India, and Japan, initiated January 1997

Vice-Chair, U.S. Global Change Research Program working group on Assessment Tools and Policy Sciences, 1994–1996

US Federal Reviewer for the Intergovernmental Panel on Climate Change working group III 1995 Report on Socioeconomics

NSF Principal for the Committee on the Environment and Natural Resources' Subcommittee on Risk Assessment, 1993–1996. Also served as the liaison between the Subcommittee on Risk Assessment and the Subcommittee on Social and Economic Sciences

Advisory panel member for Environmental Ethics and Risk Management, National Academy of Public Administration and George Washington University, 1993–1994

Science Advisory Board member for Consortium for International Earth Science Information Network, 1993

Review Panel member for Economics and the Value of Information, NOAA, 1993

NSF technical representative to the FCCSET Ad Hoc Working Group on Risk Assessment and member of its Subcommittee on Risk Assessment, 1992–1993





NSF representative to Working Party of the FCCSET Subcommittee for Global Change Research on Assessment, 1992–1993

Affirmative Action Representative for the Energy Division, Oak Ridge National Laboratory 1984–1989, AA Rep for the Central Management Organization of ORNL, October 1989 to November 1990

Board of Directors, Vice President (1987–1988), President (1988–1989), Matrix Organization, The Business Center for Women and Minorities, Knoxville, TN

## **EDITORSHIPS AND EDITORIAL REVIEW BOARDS**

Editorial Board, Journal of Risk Analysis, 1997–2012

Editorial Board, Journal of Risk Research, 1997–2005

## **PEER REVIEWER**

The Energy Journal, Climate Change, Contemporary Economic Policy, Growth and Change, Ecological Applications, Risk Analysis, Duke University Press, Princeton University Press, J. of Environmental Economics and Management, Resources and Energy, The Environmental Professional, Journal of Risk Research, National Science Foundation, National Oceanic and Atmospheric Administration, FORUM, U.S. Environmental Protection Agency

## **PROFESSIONAL AFFILIATIONS**

American Economic Association

Women's Council on Energy and the Environment

Past President, 2017-2018

President, 2015-2017

Vice President, 2011-2014

Secretary, 2007-2010

Board Member, 2004-2006

Society for Risk Analysis

Councilor, 2013

President, 2002

President-Elect, 2001

Councilor, 1996–1999

American Bar Association



## **ATTACHMENT 2**

**Robin A. Cantor, Ph.D.**  
**Managing Director**

## **EXPERT TESTIMONY IN THE LAST FOUR YEARS**

**Hooman M. Melamed, M.D., Hooman M. Melamed, M.D., Inc., and Navid Navizadeh, M.D. et al. v. Kaiser Foundation Health Plan, Inc., et al.**

Marion's Inn LLP (Defendant KFHP)

Case No. BC 432894

Superior Court of the State of California, County of Los Angeles

- Declaration (August 26, 2014)
- Declaration (March 28, 2015)
- Deposition (April 29, 2015)
- Declaration (May 5, 2015)

**Restaurant Action Alliance NYC, et al. against The City of New York, et al.**

Gibson Dunn (Petitioner)

Supreme Court of the State of New York, County of New York

- Affidavit (April 27, 2015)
- Affidavit (July 9, 2015)
- Affidavit (December 14, 2017)

**In re: Target Corporation Data Security Breach Litigation**

Zimmerman Reed, PLLP (Bank Class Plaintiffs)

US District Court of District of Minnesota

- Deposition (July 15, 2015)
- Declaration (August 25, 2015)

**Protest of Raytheon Company**

Holland & Knight (Protester)

No. B-412384

Solicitation No.: R2-3G-0839

United States Government Accountability Office, Washington DC

- Declaration (December 4, 2015)

**The Blackfeet Tribe v. United States**

Department of Justice (Defendant)

US Court of Federal Claims

Cause No. 12-429 L

- Trial Testimony (August 24, 2016)



**Florida v. Georgia**

State of Georgia (Defendant)

Supreme Court of the United States, No. 142, Original

- Deposition (July 7, 2016)
- Written Direct Testimony (October 26, 2016)

**Ingersoll Rand Company v. Affiliated FM Insurance Company, et al.**

Hinshaw & Culbertson LLP, Clausen Miller P.C., Dillon Law Group, LLC and Connell Foley LLP (Defendant)

Docket No. MID-L-252-12

Superior Court of New Jersey Law Division: Middlesex County

- Deposition (September 8, 2016)

**In re: Fluidmaster, Inc., Water Connector Components Products Liability Litigation**

Pillsbury Winthrop Shaw Pittman LLP (Defendant)

Case No. 1:14-cv-05696, MDL No. 2575

US District Court for the Northern District of Illinois Eastern Division

- Declaration (June, 2016)
- Deposition (August 5, 2016)

**Appvion, Inc. and NCR Corp. v. P.H. Glatfelter Company, et al.**

DeWitt Ross & Stevens S.C. (Plaintiff)

Case No. 2:08-cv-00016

US District Court for the Eastern District of Wisconsin

- Deposition (November 2, 2016)

**Martin et al. v. Monsanto Company**

Winston & Strawn LLP (Defendant)

US District Court for the Central District of California

Case No.:5:16-cv-02168-JFW (SPx)

- Declaration (February 20, 2017)

**Coles's Wexford Hotel, Inc. et al. v. UPMC and Highmark Inc.**

Boies Schiller Flexner, LLP (Class Plaintiffs)

US District Court for the Western District of Pennsylvania

Case No.:2:10-cv-01609-JFC

- Deposition (May 1, 2018)
- Hearing Testimony (September 19, 2018)
- Hearing Testimony (November 20, 2018)

**PolyOne Corporation v. Westlake Vinyls, Inc.**

Hanson Bridgett LLP (Petitioning Party)

JAMS Arbitration

- Deposition (June 26, 2018)
- Hearing Testimony (August 13, 2018)
- Hearing Testimony (November 30 – December 1, 2018)



**Paul Wachter, as Representative vs. Apple, Inc.**

Munger, Tolles & Olson LLP (Petitioning Party)

JAMS Arbitration

- Deposition (September 21, 2018)

**Cannon Electric Inc., et al. v. ACE Property and Casualty Company, et al.**

Morgan, Lewis & Bockius LLP (Plaintiff ITT)

Superior Court of California, County of Los Angeles

Case No. BC 290354

- Deposition (October 12, 2018)
- Trial Testimony (November 7-8, 2018)

**Catherine Papasan et al. v. Dometic Corporation**

Lash & Goldberg LLP and Weil, Gotshal & Manges LLP (Defendant)

US District Court for the Southern District of Florida

Case No. 1:16-cv-22482- SCOLA/OTAZO-REYES

- Deposition (March 12, 2019)

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**Attachment 3 - Materials Considered**  
**In Re: National Prescription Opiate Litigation**

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**Document Description**

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**Legal**

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City of Cleveland v. Amerisourcebergen Drug Corporation, et al., "Complaint for Public Nuisance, etc.," Civil Action No. 1:18-op-45132, filed March 6, 2018

City of Cleveland, Ohio, et al. v. Purdue Pharma L.P., et al., "Second Amended Corrected Complaint, Demand for Jury Trial," Case No. 1:17-md-2804, filed May 29, 2018

Corrected Second Amended Complaint, In Re National Prescription Opiate Litigation, MDL No. 2804, Case No. 17-md-2804 (referring to Case No. 18-op-45090), United States District Court for the Northern District of Ohio Eastern Division, May 18, 2018.

County of Summit, "OH's Corrected Second Am. Compl. & Jury Demand," In re National Prescription Opiate Litigation, Case No. 1:17-MD-2804 (N.D. Ohio May 29, 2018)

Second Amended Complaint, In Re National Prescription Opiate Litigation, MDL No. 2804, Case No. 17-md-2804, United States District Court for the Northern District of Ohio, Eastern Division, May 18, 2018.

The County of Cuyahoga v. Purdue Pharma L.P., et al., "Complaint For Damages," Case No. 1:17-cv-02482, filed November 27, 2017

The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al., "Second Amended Corrected Complaint, Demand for Jury Trial," Case No. 1:17-md-02804, filed May 30, 2018

The County of Summit, Ohio, et al. v. Purdue Pharma, L.P., et al., "Complaint," Case No. 5:18-cv-00170, filed January 22, 2018

The County of Summit, Ohio, et al. v. Purdue Pharma, L.P., et al., "Corrected Second Amended Complaint and Jury Demand," Case No. 1:17-md-02804, filed May 29, 2018

**Expert Reports, Depositions, and Deposition Exhibits**

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Data Appendix, *In Re National Prescription Opiate Litigation*, Apr. 25, 2019

Deposition of David Cutler, Ph.D., Vol. 1, *In Re National Prescription Opiate Litigation* (Apr. 26, 2019)

Deposition of David Cutler, Ph.D., Vol. 2, *In Re National Prescription Opiate Litigation* (Apr. 27, 2019)

Deposition of Eric A. Griffin, *In Re National Prescription Opiate Litigation* (Jan. 23, 2019)

Deposition of Jonathan Gruber, Ph.D., *In Re National Prescription Opiate Litigation* (Apr. 25, 2019)

Deposition of Matthew Perri, III, BS Pharm, Ph.D., RPh, Vol. 1, *In Re National Prescription Opiate Litigation* (Apr. 23, 2019)

Deposition of Matthew Perri, III, BS Pharm, Ph.D., RPh, Vol. 2, *In Re National Prescription Opiate Litigation* (Apr. 24, 2019)

Deposition of Thomas G. McGuire, Ph.D., Vol. 1, *In Re National Prescription Opiate Litigation* (Apr. 23, 2019)

Deposition of Thomas G. McGuire, Ph.D., Vol. 2, *In Re National Prescription Opiate Litigation* (Apr. 30, 2019)

Expert Report of Matthew Perri III, B.S. Pharm, Ph.D., RPh, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019)

Expert Report of Professor David Courtwright, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019)

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Expert Report of Professor David Cutler, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019) and supporting materials

Expert Report of Professor Jonathan Gruber, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019) and supporting materials

Expert Report of Professor Meredith Rosenthal, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019) and supporting materials

Expert Report of Professor Thomas McGuire: Damages to Bellwethers, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019) and supporting materials

Expert Report of Professor Thomas McGuire: Regarding Public Nuisance, *In Re National Prescription Opiate Litigation* (Mar. 25, 2019) and supporting materials

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**Bates Stamped Files**

County of Summit 2017 Budget - Total Expenditures. (SUMMIT\_000007600)

County of Summit Children Services Operating Forecast - As of December 31, 2018. (SUMMIT\_002057610)

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**Data Sources**

Drug Enforcement Agency ARCOS Retail Drug Summary Reports (RDSR)

IQVIA (formerly IMS Health), Integrated Promotional Services data (IPS)

IQVIA (formerly IMS Health), National Prescription Audit data (NPA)

IQVIA (formerly IMS Health), National Sales Perspectives data (NSP)

IQVIA (formerly IMS Health), Xponent data (ALLERGAN\_MDL\_02485011, ALLERGAN\_MDL\_02949563, ALLERGAN\_MDL\_03281086)

Medical and Pharmacy Claims Data in Track One Cases (PLTF\_2804\_000018913.zip)

Medical Examiner data (CUYAH\_000099975.xlsx and SUMMIT\_000087427.xlsx)

NCHS Multiple Causes of Death Data

Survey of Inmates in Local Jails, 2002 [United States] (ICPSR 4359). Available at <https://www.icpsr.umich.edu/icpsrweb/ICPSR/studies/4359>.

USDA Livestock and Meat International Trade Data. "Sheep and goats: Monthly U.S. trade - All months and counties" Available at [https://www.ers.usda.gov/webdocs/DataFiles/81475/SheepGoat\\_MonthlyFull.xlsx?v=3560.2](https://www.ers.usda.gov/webdocs/DataFiles/81475/SheepGoat_MonthlyFull.xlsx?v=3560.2)

County of Summit, Ohio Comprehensive Annual Financial Report for the year ended December 31, 2015.

County of Summit, Ohio Comprehensive Annual Financial Report for the year ended December 31, 2017.

County of Cuyahoga, Ohio Annual Information Statement for fiscal year ended 12/31/17.

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**Publicly Available Materials**

21 CFR Part 1308, Drug Enforcement Administration, "Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II," (Aug. 22, 2014), available at [https://www.deadiversion.usdoj.gov/fed\\_regs/rules/2014/fr0822.htm](https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm).

Academy of Managed Care Pharmacy, "AMCP Guide to Pharmaceutical Payment Methods," available at [http://www.amcp.org/data/jmcp/JMCPSUPPC\\_OCT07.pdf](http://www.amcp.org/data/jmcp/JMCPSUPPC_OCT07.pdf)

Allen, Mark et al., "Reference Guide on Estimation of Economic Damages."

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- American Academy of Pediatrics, "America's Opioid Crisis: The Unseen Impact on Arkansas Children," AAP, *available at* [https://www.aap.org/en-us/advocacy-and-policy/federal-advocacy/Documents/Opioid-StateFactsheets/opioid\\_fs\\_arkansas.pdf](https://www.aap.org/en-us/advocacy-and-policy/federal-advocacy/Documents/Opioid-StateFactsheets/opioid_fs_arkansas.pdf).
- Appropriate Use of IMS Information, "Financial Community Presentation," (Nov. 12, 2009) *available at* [http://us.imshealth.com/marketing/fincom/appropriateuse\\_presentation.pdf](http://us.imshealth.com/marketing/fincom/appropriateuse_presentation.pdf)
- Azoulay, Pierre, "Do Pharmaceutical Sales Respond to Scientific Evidence?," *Journal of Economics & Management Strategy* 11, no. 4 (2002), 51-594.
- Baker, Jonathan B., Daniel L. Rubinfeld, Empirical Methods in Antitrust Litigation: Review and Critique. *American Law and Economics Review*, 1(1/2), (1999).
- Benner, K., "Snaring Doctors And Drug Dealers, Justice Dept. Intensifies Opioid Fight," New York Times (Aug. 22, 2018), *available at* <https://www.nytimes.com/2018/08/22/us/politics/opioids-crackdown-sessions.html>.
- Berndt, Ernst R., "Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price." *Journal of Economic Perspectives*. 16:4, (2002).
- Berndt, Ernst R., et al., "Information, Marketing, and Pricing in the U.S. Antiulcer Drug Market," *The American Economic Review* 85, no. 2 (1995).
- Berndt, Ernst R., et al., "The Roles of Marketing, Product Quality, and Price Competition in the Growth and Composition of the U.S. Antiulcer Drug Industry," *The Economics of New Good*, edited by Bresnahan, Timothy F. and Gordon, Robert J., 277-328 Chicago: University of Chicago Press, 1996.
- Bernstein, Lenny, "HHS launches program to cut opioid overdoses by 40 percent in three years," *The Washington Post*, April 18, 2019, [https://www.washingtonpost.com/national/health-science/hhs-launches-program-to-cut-opioid-overdoses-by-40-percent-in-three-years/2019/04/18/78f11b00-620f-11e9-9ff2-abc984dc9eec\\_story.html?utm\\_term=.cfb909c07c49](https://www.washingtonpost.com/national/health-science/hhs-launches-program-to-cut-opioid-overdoses-by-40-percent-in-three-years/2019/04/18/78f11b00-620f-11e9-9ff2-abc984dc9eec_story.html?utm_term=.cfb909c07c49).
- Bonnie, R., Ford M, Phillips J, "Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use," *The National Academies of Sciences*, (2017).
- Bureau of Justice. Survey of Inmates In Local Jails (SILJ). 2002, *available at* <https://www.bjs.gov/index.cfm?ty=dcdetail&iid=274>.
- Butikofer, A and M. M. Skira, "Missing Work is a Pain: The Effect of Cox-2 Inhibitors on Sickness Absence and Disability Pension Receipt," *Journal of Human Resources*, 2018, 53(1).
- Case, Anne and Angus Deaton, "Mortality and Morbidity in the 21st Century," *Brookings Papers on Economic Activity* (Spring 2017), 397-476.
- Case, Anne and Angus Deaton, "Deaths of despair redux: a response to Christopher Ruhm," (2018).
- Caulkins, J. and Kleiman, M. "How Much Crime is Drug-Related? History, Limitations, and Potential Improvements of Estimation Methods", *U.S. Department of Justice*, (April 2014).
- Center for Medicare & Medicaid Services, "HCAHPS Fact Sheet," (Nov. 2017) *available at* [https://www.hcahpsonline.org/globalassets/hcahps/facts/hcahps\\_fact\\_sheet\\_november\\_2017.pdf](https://www.hcahpsonline.org/globalassets/hcahps/facts/hcahps_fact_sheet_november_2017.pdf).
- Center for Medicare & Medicaid Services, "HCAHPS: Patient Perspectives of Care Survey," *available at* <https://www.cms.gov/Medicare/Quality-Initiatives-patient-assessment-instruments/hospitalqualityinits/hospitalhcahps.html>.
- Centers for Disease Control and Prevention, "Opioid Basics", (Dec. 19, 2018) *available at* <https://www.cdc.gov/drugoverdose/opioids/index.html>.
- Centers for Medicare and Medicaid Services, "History," *available at* <https://www.cms.gov/About-CMS/Agency-Information/History/index.html>.



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- Cohen, Ronnite, "Dentists routinely prescribe opioids to teens, putting them at risk of addiction: 'These are kids who could have gotten Advil'," *The Chicago Tribune*, March 4, 2019, <https://www.chicagotribune.com/lifestyles/health/sc-hlth-dentists-giving-teens-opioids-0304-story.html>.
- Committee on Homeland Security and Governmental Affairs Report, "Combatting the Opioid Crisis: Exploiting Vulnerabilities in International Mail", (January 23, 2018).
- Committee on Ways and Means U.S. House of Representatives. "To Review Proposals to Improve Child Protective Services", (May 23, 2006).
- Danzon, P., "Price Discrimination for Pharmaceuticals: Welfare Effects in the US and the EU," *International Journal of the Economics of Business* (1997) 4(3): 301-321.
- Dayer, Lindsey, Jacob T. Painter, Kelsey McCain, Jarrod King, Julia Cullen & Howell R. Foster, "A recent history of opioid use in the US: Three decades of change," *Substance Use & Misuse* 54:2, 331-339 (2019).
- Dowell, Haegerich, and Chou. "CDC Guideline For Prescribing Opioids For Chronic Pain — United States, 2016." *MMWR. Recommendations and Reports* 65.1 (2016): 1-49, (March 15, 2016)
- Dworksy, A., "Families at the Nexus of Housing and Child Welfare," *Chaplin Hall at the University of Chicago*, (Nov. 2014).
- Federation of State Medical Boards, "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain," Euless, Texas: Federation of State Medical Boards, (1998).
- Fonseca, Rafael and Tucker, John, "Are Doctors Bribed by Pharma? An Analysis of Data," July 21, 2018, <http://thehealthcareblog.com/blog/2018/07/21/are-doctors-bribed-by-pharma-an-analysis-of-data/>.
- Franklin, Gary M. "Opioids for chronic noncancer pain." *Neurology* 83.14 (2014).
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- Gaskin, D.J. and P. Richard, "The Economic Cost of Pain in the United States," *The Journal of Pain*, 13(8), 2012.
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- Goldman, Dana P. et al., "Prescription drug cost sharing: associations with medication and medical utilization and spending and health." *The Journal of the American Medical Association*, (July 2007).
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